

EXHIBIT 1



**Service of Process
Transmittal**

03/08/2018

CT Log Number 532926829

TO: Carol Purcell
Endo Pharmaceuticals Inc.
1400 Atwater Dr
Malvern, PA 19355-8701

RE: Process Served in Delaware

FOR: Endo Pharmaceuticals Inc. (Domestic State: DE)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION: MSPA CLAIMS 1, LLC, etc., et al., Pltfs. vs. ANDA, INC., etc., et al., Dfts. // TO: Endo Pharmaceuticals Inc.

DOCUMENT(S) SERVED: Summons, Complaint

COURT/AGENCY: Miami-Dade County Court, FL
Case # 2018005066CA01

NATURE OF ACTION: Product Liability Litigation - Deceptive marketing practices relating to prescription Opioids

ON WHOM PROCESS WAS SERVED: The Corporation Trust Company, Wilmington, DE

DATE AND HOUR OF SERVICE: By Process Server on 03/08/2018 at 14:30

JURISDICTION SERVED : Delaware

APPEARANCE OR ANSWER DUE: Within 20 days after service

ATTORNEY(S) / SENDER(S): James L. Ferraro
THE FERRARO LAW FIRM, P.A.
600 Brickell Avenue
38th Floor
Miami, FL 33131
305-375-0111

ACTION ITEMS: CT has retained the current log, Retain Date: 03/09/2018, Expected Purge Date: 03/14/2018

Image SOP

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TO: Carol Purcell
Endo Pharmaceuticals Inc.
1400 Atwater Dr
Malvern, PA 19355-8701

RE: Process Served in Delaware

FOR: Endo Pharmaceuticals Inc. (Domestic State: DE)

Email Notification, Stephanie Stidham stidham.stephanie@endo.com

SIGNED: The Corporation Trust Company
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Wilmington, DE 19801-1120
TELEPHONE: 302-658-7581

Filing # 68333788 E-Filed 02/22/2018 02:42:02 PM

IN THE CIRCUIT COURT OF THE
ELEVENTH JUDICIAL CIRCUIT IN AND
FOR MIAMI-DADE COUNTY, FLORIDA
GENERAL JURISDICTION DIVISION

CASE NO.: 2018-005066-CA-01

MSPA CLAIMS 1, LLC, a Florida Limited
Liability Company;
MAO-MSO RECOVERY II, LLC a Delaware
Limited Liability Company;
MSP RECOVERY CLAIMS, SERIES LLC, a
Delaware Limited Liability Company;

Plaintiffs,

"CLASS REPRESENTATION"

-vs-

ANDA, INC., a Florida Profit Corporation;
TEVA PHARMACEUTICALS INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.;
PURDUE PHARMA, L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS,
INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN
PHARMACEUTICALS, INC.;
NORAMCO, INC.;
ENDO HEALTH SOLUTIONS, INC.;
ENDO PHARMACEUTICALS, INC.;
QUALITEST PHARMACEUTICALS, INC.;
ALLERGAN PLC, f/k/a ACTAVIS PLC;
WATSON PHARMACEUTICALS, INC., n/k/a
ACTAVIS, INC.;
WATSON LABORATORIES, INC.;
ACTAVIS LLC;
ACTAVIS PHARMA, INC., f/k/a WATSON
PHARMA, INC.;
MALLINCKRODT PLC;
MALLINCKRODT LLC;

MCKESSON CORPORATION;
CARDINAL HEALTH INC.;
AMERISOURCEBERGEN DRUG CORPORATION;
ABBOTT LABORATORIES, INC.;
RUSSELL PORTENOY;
PERRY FINE;
SCOTT FISHMAN; and
LYNN WEBSTER,

Defendants.

CIVIL ACTION SUMMONS 20 DAY CORPORATE SERVICE

TO: ENDO PHARMACEUTICALS, INC.
c/o CORPORATION TRUST CO.,
1209 Orange Street
Wilmington, DE 19801

A lawsuit has been filed against you. You have 20 calendar days after this summons is served on you to file a written response to the attached Complaint with the clerk of the court. A phone call will not protect you; your written response, including the case number given above the names of the parties, must be filed if you want the Court to hear your side of the case. If you do not file your response on time, you may lose the case, and your wages, money and property may thereafter be taken without further warning from the Court. There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may call an attorney referral service or legal aid office (listed in the phone book).

If you choose to file a written response yourself, at the same time you file your written response to the Court, located at:

Miami-Dade County Courthouse
Clerk of Courts
Room 133
73 West Flagler Street
Miami, Florida 33130

You must also mail or take a copy of your written response to the "Plaintiff/Plaintiff's Attorneys" named below.

THE FERRARO LAW FIRM, P.A.

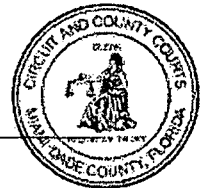
Janpaul Portal, Esq.
Brickell World Plaza
600 Brickell Avenue
Suite 3800
Miami, Florida 33131
Tel. (305) 375-0111
Fax (305) 379-6222

TO EACH SHERIFF OF THE STATE OF FLORIDA: You are commanded to service this Summons, a copy of the Complaint of this lawsuit, a First Set of Interrogatories and a First Request for Production on the above named defendant.

HARVEY RUVIN
CLERK OF COURTS

2/28/2018

BY Gonelle Brown 164659
DEPUTY CLERK



(Court Seal)

**AMERICANS WITH DISABILITIES ACT OF 1990
ADA NOTICE**

"If you are a person with a disability who needs any accommodation in order to participate in this proceeding, you are entitled, at no cost to you, to the provision of certain assistance. Please contact the Eleventh Judicial Circuit Court's ADA Coordinator, Lawson E. Thomas Courthouse Center, 175 NW 1st Ave., Suite 2702, Miami, FL 33128, Telephone (305) 349-7175; TDD (305) 349-7174, Fax (305) 349-7355 at least 7 days before your scheduled court appearance, or immediately upon receiving this notification if the time before the scheduled appearance is less than 7 days; if you are hearing or voice impaired, call 711."



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CT Log Number 532926801

TO: Carol Purcell
Endo Pharmaceuticals Inc.
1400 Atwater Dr
Malvern, PA 19355-8701

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FOR: Endo Health Solutions Inc. (Domestic State: DE)

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TITLE OF ACTION: MSPA CLAIMS 1, LLC, etc., et al., Pltfs. vs. ANDA, INC., etc., et al., Dfts. // To: Endo Health Solutions, Inc
Name discrepancy noted.

DOCUMENT(S) SERVED: Summons, Complaint

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Email Notification, Jobina Jones-McDonnell jones.jobina@endo.com

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Email Notification, Marian Gustafson marian.gustafson@parpharm.com

Email Notification, Carolyn Hazard hazard.carrie@endo.com

Email Notification, Par Notice Dept Par.noticeDept@parpharm.com

Email Notification, Carol Purcell Purcell.Carol@endo.com



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Plaintiffs,

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-VS-

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ALLERGAN PLC, f/k/a ACTAVIS PLC;
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PHARMA, INC.;
MALLINCKRODT PLC;
MALLINCKRODT LLC;

MCKESSON CORPORATION;
CARDINAL HEALTH INC.;
AMERISOURCEBERGEN DRUG CORPORATION;
ABBOTT LABORATORIES, INC.;
RUSSELL PORTENYO;
PERRY FINE;
SCOTT FISHMAN; and
LYNN WEBSTER,

Defendants.

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TO: ENDO HEALTH SOLUTIONS, INC.
c/o CORPORATION TRUST CO.,
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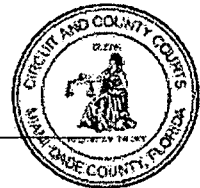
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BY Gonelle Brown 164659
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GENERAL JURISDICTION DIVISION

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CEPHALON, INC.;
PURDUE PHARMA, L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
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AMERISOURCEBERGEN DRUG CORPORATION;
ABBOTT LABORATORIES, INC.;
RUSSELL PORTENOY;
PERRY FINE;
SCOTT FISHMAN; and
LYNN WEBSTER,

Defendants.

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	SUMMARY OF THE ACTION.....	3
	A. The Opioid Epidemic.....	3
	B. Defendants' Fraudulent and Highly Deceptive Marketing Campaign and Intentional Misconduct.....	8
III.	THE PARTIES.....	14
	A. Plaintiffs.....	14
	B. Defendants.....	18
	1. Manufacturer Defendants.....	18
	2. Distributor Defendants.....	29
	3. Key Opinion Leaders.....	37
IV.	JURISDICTION AND VENUE.....	38
V.	STANDING.....	40
	A. Medicaid and Third-Party Liability.....	40
	B. Florida's Statewide Medicaid Managed Care Program.....	47
	C. Plaintiffs' Rights Under their Assignment Agreements.....	51
	1. Plaintiffs' Valid and Binding Assignment Agreements.....	51
	2. Representative Assignment Agreement with Preferred Medical Plan, Inc., a Florida MCO/HMO and Participating MMA Plan.....	53
	3. Representative Assignment Agreement with Interamerican Medical Center Group, LLC, a Florida Medicaid Provider and MSO/IPA.....	56
	4. Representative Assignment Agreement with Trinity Physicians, LLC, a Florida Medicaid Provider and MSO.....	58

VI.	FACTS RELEVANT TO ALL CAUSES.....	61
A.	The Pain-Relieving and Addictive Properties of Opioids.....	61
B.	Defendants Used Multiple Avenues to Disseminate Their False and Deceptive Statements About Opioids.....	65
1.	Defendants Trivialized the Risks of Long Term and Higher Dosage Opioid Therapy.....	66
2.	Defendants Used a Diverse Group of Seemingly Independent Third Parties to Spread False and Deceptive Statements About the Risks and Benefits of Opioids.....	77
a.	Key Opinion Leaders ("KOLs").....	78
b.	Front Groups.....	84
(1)	American Pain Foundation ("APF").....	85
(2)	American Academy of Pain Medicine ("AAPM").....	87
C.	Opioid Therapy Makes Patients Sicker Without Long Term Benefits	90
D.	Defendants' Scheme to Change Prescriber Habits and Public Perception	91
1.	Defendants' Corruption of Scientific Literature.....	93
2.	Defendants' Misuse of Treatment Guidelines.....	95
a.	Federation of State Medical Boards (FSMB).....	95
b.	AAPM/APS Guidelines.....	96
c.	Guidelines that Did Not Receive Defendants' Support.....	97
E.	Defendants' Promotion of Their Opioid Drugs Was Also Deceptive.....	98
F.	Defendants Knew That Their Marketing of Chronic Opioid Therapy Was False Unfounded, and Dangerous and Would Harm Plaintiffs.....	99
G.	Defendants Entered into and Engaged in a Civil Conspiracy.....	100
VII.	CLASS REPRESENTATION ALLEGATIONS PURSUANT TO FLORIDA RULE OF CIVIL PROCEDURE 1.220.....	101

A.	Class Definition.....	101
B.	Numerosity.....	103
C.	Commonality.....	104
D.	Typicality.....	105
E.	Adequacy of Representation.....	106
F.	Superiority and Manageability.....	107
VIII.	CAUSES OF ACTION.....	108
A.	Count I – Violation of the Florida Deceptive and Unfair Trade Practices Act, Florida Statute § 501.201, et seq. (“FDUPTA”).....	108
B.	Preamble for Counts II and III – Florida Racketeer Influenced and Corrupt Organizations Act (“Florida Civil RICO”).....	114
C.	Count II – Violation of Florida Statute § 895.03 – Opioid Drugs Promotion Enterprise Pursuant to Florida RICO.....	115
D.	Count III – Violation of Florida Statute § 895.03 – RICO Conspiracy Pursuant to Florida RICO.....	121
E.	Count IV – Private Cause of Action Under the Florida Medicaid Third-Party Liability Act, Florida Statute § 409.910.....	125
F.	Count V – Fraudulent Concealment.....	128
G.	Count VI – Conspiracy to Commit Fraud by Concealment.....	131
H.	Count VII – Negligence and Gross Negligence against the Manufacturer Defendants.....	134
I.	Count VIII – Negligence and Gross Negligence against the Distributor Defendants.....	137
J.	Count IX – Unjust Enrichment.....	138
IX.	DEMAND FOR JURY TRIAL.....	140
X.	PRAYER FOR RELIEF.....	140

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

The Plaintiffs, MSPA CLAIMS 1, LLC, a Florida Limited Liability Company, MAO-MSO RECOVERY II, LLC, a Delaware Limited Liability Company, and MSP RECOVERY CLAIMS, SERIES LLC, a Delaware Limited Liability Company, on behalf of themselves and a Class of similarly-situated entities and their assignees, by and through undersigned counsel, hereby bring this Class Action seeking relief from the Defendants, ANDA, INC., a Florida Profit Corporation, TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, ABBOTT LABORATORIES, INC., RUSSELL PORTENYOY, PERRY FINE, SCOTT FISHMAN, and LYNN WEBSTER, and allege as follows:

I. INTRODUCTION

1. The Plaintiffs, MSPA CLAIMS 1, LLC, MAO-MSO RECOVERY II, LLC, and MSP RECOVERY CLAIMS, SERIES LLC (hereinafter collectively referred to as "Plaintiffs"),

in their capacity as assignees of certain Florida Medicaid Managed Care Plans and Providers,¹ including, but not limited to, Managed Care Organizations, Pre-Paid Inpatient Health Plans, Pre-Paid Ambulatory Health Plans, Health Maintenance Organizations, Managed Service Organizations, Provider Service Networks, Exclusive Provider Organizations, Accountable Care Organizations, Primary Care Case Management entities, Independent Physician Associations, and First Tier, Downstream and Related Entities, that contracted with and/or were licensed by AHCA to provide health care benefits and related services to Florida Medicaid beneficiaries (collectively referred to as “Plaintiffs’ Assignors”),² and on behalf of a Class of similarly-situated entities, bring this action against the Defendant opioid manufacturers, distributors and key opinion leaders.

2. The Plaintiffs’ Assignors and putative Class Members have the unique position of being “payors of last resort” in that they stand in the same shoes as AHCA because they have entered into risk contracts³ to provide health care benefits and additional services to Florida Medicaid beneficiaries (hereinafter referred to as the “PLR Class”). As such, the Plaintiffs and PLR Class have the same or similar responsibilities, limitations, and the same or similar rights and responsibilities of pursuing third-party liability claims when delegated that authority pursuant to the applicable Florida law or by contract. The numerous Florida Medicaid contracted entities that assigned their rights to Plaintiffs, as well as the Florida Medicaid entities that make up the PLR Class, provide health care benefits and services to millions of Florida Medicaid beneficiaries,

¹ Medicaid, as used herein, means the joint federal-state medical assistance program authorized by Title XIX of the Social Security Act, 42 U.S.C. § 1396, et seq., and regulations thereunder, as administered in the State of Florida by the Agency for Health Care Administration (“AHCA”) under § 409.901, Florida Statutes, et seq.

² The Plaintiffs assert the rights of Plaintiffs’ Assignors via contractual assignment of all rights, title, and interest allowing them to bring these claims.

³ “Risk contracts” means a Medicaid contract whereby the contractor: (1) assumes risk for the contract for the cost of the services under the contract; and (2) incurs loss if the cost of furnishing the services exceeds the payments under the contract. See 42 CFR § 438.2.

including a significant number of beneficiaries that purchased and used prescription opioids that were manufactured, marketed, promoted, sold and/or distributed by the Defendant manufactures, distributors and key opinion leaders.

3. The Defendants have earned billions of dollars peddling their addictive and life-threatening opioid drugs while systematically and intentionally misleading doctors, hospitals, patients, federal and state regulators and health insurers about the true risks of opioid addiction. The Defendant manufacturers and distributors have engaged in an intentional, decades-long pattern of fraudulent and deceptive acts relating to the efficacy of their respective opioid drugs, intentionally diminishing the associated health hazards and conspiring with key opinion leaders to increase their sales and profits despite the known risks and dangerous propensity of their drugs.

4. The Plaintiffs' Assignors and Medicaid entities that make up the PLR Class, were ultimately forced to pay for and absorb the losses related to the delivery of care, services and/or supplies, including, the delivery of opioid medications, treatments, hospitalizations, addiction and rehabilitation treatment, overdose or other opioid-related health care services to their respective Florida Medicaid beneficiaries.

II. SUMMARY OF THE ACTION

A. THE OPIOID EPIDEMIC

5. Opioid addiction, abuse and overdose deaths have created a national health crisis and have become a public health emergency in the State of Florida.⁴ The opioid epidemic has directly impacted Florida's families and children in almost every county throughout the state.

⁴ On May 3, 2017, Governor Rick Scott declared the opioid epidemic a public health emergency in Florida citing to statistics from the CDC finding that in 2015, opioids were responsible for over 33,000 deaths nationwide and nearly 3,900 deaths in Florida. *See* Executive Order 2017-146 (2017). Available at http://www.flgov.com/wp-content/uploads/orders/2017/EO_17-146.pdf. *See also*, Executive Orders 2017-177 and 2017-230 (2017).

Moreover, the opioid epidemic has placed a substantial economic burden on Florida's healthcare system and, mainly, on Florida's Medicaid program.

6. Opioids include brand-name drugs like OxyContin and Percocet and generics like oxycodone and hydrocodone.⁵ They are derived from or possess properties similar to opium and heroin. They are highly addictive and dangerous and, therefore, are regulated by the United States Food and Drug Administration ("FDA") as controlled substances.⁶ Opioids provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days.

7. Opioid analgesics, however, are highly addictive⁷ and subject to abuse, particularly when used long-term for chronic non-cancer pain (pain lasting three months or longer, hereinafter referred to as "chronic pain"). Opioids are widely diverted and improperly used, and the widespread abuse of opioids has resulted in the national epidemic of opioid overdose deaths and addiction.⁸ The opioid epidemic is "directly related to the increasingly widespread misuse of

⁵ The term "opioid," as used herein, refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

⁶ Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

⁷ See Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) ("DSM-V") (Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction.). The term "addiction," as used herein, refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

⁸ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain— Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253(2016).

powerful opioid pain medications.”⁹

8. On August 10, 2017, President Trump declared the opioid epidemic a national public health emergency impacting nearly every community across all 50 states.¹⁰ According to the U.S. Centers for Disease Control and Prevention (“CDC”), the nation has been swept up in an opioid-induced public health crisis.¹¹

9. Since 2000, more than 300,000 Americans have lost their lives to an opioid overdose. *See id.* The CDC found that the amount of opioids prescribed in 2015 was enough for every American to be medicated around the clock for 3 weeks. *Id.* The CDC also found that in 2015 more than 52,000 people died from a drug overdose; of those, 33,091 (63.1%) involved a prescription or illicit opioid. *Id.* The CDC estimated that 2.0 million persons in the United States had opioid use disorder (addiction) associated with prescription opioids in 2015. In fact, the CDC found that prescription opioid-related overdose deaths and admissions for treatment of opioid use disorder have increased in parallel with increases in opioids prescribed in the United States, which quadrupled between 1999 and 2010. *See id.* The CDC further concluded that the increase was primarily due to use of opioids to treat chronic non-cancer pain. *See id.*

10. Florida has been at the epicenter of the opioid epidemic, especially in the hardest hit counties like Miami-Dade, Palm Beach, Broward, Brevard, Duval, Pinellas and Orange, as well as in numerous counties in the Pan Handle.¹² In 2016, 5,725 opioid-related deaths were reported

⁹*See* Robert M. Califf et al., A Proactive Response to Prescription Opioid Abuse, 374 N. Eng. J. Med. 1480 (2016).

¹⁰ *The President's Commission on Combating Drug Addiction and the Opioid Crisis*. 2017, Nov. 21. https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

¹¹ CDC, *New data show continuing opioid epidemic in the United States*. 2016, Dec. 16. <https://www.cdc.gov/media/releases/2016/p1216-continuing-opioid-epidemic.html>; Guy, Jr. GP, Zhang K, et al., Vital Signs: Changes in Opioid Prescribing in the United states, 2006-2015. MMWR Morb Mortal Wkly Rep 2017;66:697-704.

¹² Florida Medical Examiner's Commission. Drugs identified in Deceased Persons, 2016 Report. Florida

in Florida, which represents a 35% increase from 2015, including, a 28% increase in oxycodone-related deaths. *See id.* Florida also experienced a resurgence in heroin and fentanyl use leading to a significant increase in heroin-related deaths (30% increase) and fentanyl-related deaths (97% increase). *Id.* Four in five new heroin users began by misusing opioid prescription pain medications.¹³

11. Opioid addiction and abuse has also led to large increases in substance abuse treatment admissions and hospitalizations. According to the Florida Department of Children and Families (“DCF”) Substance Abuse and Mental Health Program, opioids accounted for 11.7% of all substance abuse treatment admissions during 2013.¹⁴ This represents a 24% increase compared to 2010 when 9.4% of all substance abuse treatment admissions were due to opioids. The increase in opioid treatment-related admissions can largely be attributed to the growing heroin addiction and abuse rates. For example, heroin primary treatment admissions in Miami-Dade County increased 62% between 2010 (183 admissions) and 2013 (294 admissions).

12. As a further example of the devastating toll the opioid epidemic has taken on Florida’s communities, in June 2017, the Miami-Dade Opioid Addiction Task Force reported that in Miami-Dade County alone: (1) in 2016, 229 people died from opioid poisoning, more than double the approximate 100 deaths recorded between 2000 and 2015; (2) between 2015 and 2016, fatal opioid overdoses for people in their mid-20s and early 30s increased by 98%; (3) between 2013 and 2016, opioid overdose deaths among males quadrupled; (4) in 2015, 83 deaths were

Department of Law Enforcement, Medical Examiner’s Commission, November 2017.

¹³ Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002-2004 and 2008-2010. *Drug Alcohol Depend.* 2013 Sep 1; 132 (1-2): 95-100.

¹⁴<http://www.dcf.state.fl.us/programs/samh/substanceabuse/docs/opioid/Florida%20STR%20Project%20Narrative.pdf>

attributed to heroin, which was almost 8 times more than the number of heroin-related deaths in 2011; (5) between 2014 and 2016, fentanyl and/or fentanyl analogs were identified in 376 deaths; and (6) since September 2016, fentanyl analogs have been identified in approximately 150 deaths.¹⁵ The Task Force also reported that when individuals with opioid use disorder experience greater difficulty obtaining prescription opioids many of them switch to heroin. *See id.* Heroin, however, also brings higher risks of overdose and infectious diseases, such as HIV and Hepatitis C. *Id.*

13. The opioid epidemic has also placed a substantial economic burden on Florida's healthcare system. In its report on Florida's Opioid State Targeted Response Project, DCF cited to a 2016 analysis of 58 million diagnostic and billing records from 302 Florida hospitals from all 67 counties performed by the Palm Beach Post.¹⁶ In its analysis, The Post found that the costs linked to heroin-related overdoses, Hepatitis C, bacterial infections and neonatal abstinence syndrome ("NAS") exceeded \$1.1 billion per year as of October 2015 (or \$4.1 million per day).¹⁷ The analysis further found that **Florida's Medicaid program was billed \$2.1 billion as the primary insurer** for the hospitalizations over a six-year period. *See id.* (emphasis added). The report also found that:

- a. By late 2015, the hospital billings averaged approximately \$1 million a day more than in 2010;
- b. Charges for Hepatitis C patients who used opiates was \$731,000 a day higher in 2015 than in 2010, which coincided with a 171% increase in heroin and opium overdoses;

¹⁵ Miami-Dade County Opioid Addiction Task Force Final Report (June 2017). <http://www.miamidade.gov/mayor/library/opioid-task-force/opioid-final-report-06-13-17.pdf>.

¹⁶ *See* note 14, *supra*.

¹⁷ Beall, P. & Stucka, M. (2016). Cost of Heroin Epidemic Tops \$2 Billion a Year in Florida. *Palm Beach Post*. Retrieved from www.mypalmbeachpost.com/news/cost-heroin-epidemic-tops-billion-year-florida/WYamI7pzwIHMkFkf3mzY8H/.

- c. Cases of drug addicted newborns (NAS) rose by double digits. The associated costs for their care was over \$967 million between 2010 and 2015, with five of every six dollars being billed to Florida's Medicaid program;
- d. Of these charges, there were 97 "million dollar babies" whose treatment costs exceeded seven figures each; and
- e. Florida's Medicaid program was billed \$842 million of the total costs for these drug-addicted babies.

Id.

B. DEFENDANTS' FRAUDULENT AND HIGHLY DECEPTIVE MARKETING CAMPAIGN AND INTENTIONAL MISCONDUCT

14. At all times material, Defendants knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (*i.e.*, not longer than 90 days) in managed settings (*e.g.*, hospitals) where the risk of addiction and other adverse outcomes was significantly minimized. Indeed, the FDA has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.¹⁸

15. Defendants also knew that, with long-term use, the effectiveness of opioids wanes, requiring increases in doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction.¹⁹

16. Despite the foregoing knowledge, in order to expand the market for opioids and realize blockbuster profits, Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public that would encourage the use of opioids for longer periods of time and to treat a wider range of problems,

¹⁸ Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re docket No. FDA-2012-P-0818 (Sept. 10, 2013).

¹⁹ See, *e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994).

including such common aches and pains as lower back pain, arthritis, and headaches.

17. Defendants accomplished that false perception through a coordinated, sophisticated, and highly deceptive marketing campaign that began in the late 1990s, became more aggressive in or about 2006, and continues to the present.

18. Defendants engaged in a practice and pattern of gross negligence and reckless disregard for the health and safety of consumers using prescription opioids by flooding the pharmaceutical market with dramatic increases in prescription thresholds without justification. The Defendants, individually and collectively, provided millions of opioid prescription drugs to countless pharmacies nationwide, without accountability and despite the Defendants' knowledge of suspicious orders.

19. Defendants, individually and collectively, knowing that long-term opioid use causes addiction, misrepresented the dangers of long-term opioid use to physicians, pharmacists, and patients by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

20. Defendants' marketing campaign has been extremely successful in expanding opioid use. Since 1999, the amount of prescription opioids sold in the U.S. has nearly quadrupled.²⁰ In 2010, 254 million prescriptions for opioids were filled in the U.S. – enough to medicate every adult in America around the clock for a month. In that year, 20% of all doctors' visits resulted in the prescription of an opioid (nearly double the rate in 2000).²¹ While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around

²⁰ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic. Available at: <http://www.cdc.gov/drugoverdose/epidemic/index.html>.

²¹ M. Daubresse, et al., Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010, 51(10) Med. Care 870-78 (2013).

the world and 99% of the global hydrocodone supply.²² By 2014, nearly two million Americans either abused or were dependent on opioids.²³

21. Defendants' campaign has been extremely profitable for them generating billions of dollars from addictive prescription opioids. In 2012 alone, opioids generated \$8 billion in revenue for drug companies.²⁴ Of that amount, \$3.1 billion went to Defendant Purdue for its OxyContin sales.²⁵

22. Defendants' marketing campaign has been extremely harmful to Americans. Overdoses from prescription pain relievers are a driving factor in a 15-year increase in opioid overdose deaths. Deaths from prescription opioids have also quadrupled since 1999. From 2000 to 2014 nearly half a million-people died from such overdoses. Seventy-eight Americans die every day from an opioid overdose.²⁶

23. In 2012, an estimated 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.²⁷ Between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.²⁸

24. Opioid addiction and overdose have reached epidemic levels over the past decade.

²² L. Manchikanti, et al., Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten- Year Perspective, 13 Pain Physician 401-435 (2010).

²³ CDC, Injury Prevention & Control: Opioid Overdose, Prescription Opioids. Available at: <http://www.cdc.gov/drugoverdose/opioids/prescribed.html>.

²⁴ B. Meier & B. Marsh, *The Soaring Cost of the Opioid Economy*, N.Y. Times (June 22, 2013).

²⁵ K. Eban, *Purdue Pharma's Painful Medicine*, Fortune Magazine (Nov. 9, 2011).

²⁶ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

²⁷ Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H- 46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

²⁸ J. Boscarino et al., Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system, 105(10) *Addiction* 1776 (2010); J. Boscarino et al., Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria, 30(3) *Journal of Addictive Diseases* 185 (2011).

On March 22, 2016, the FDA recognized opioid abuse as a “public health crisis” that has a “profound impact on individuals, families and communities across our country.”²⁹ Defendants’ marketing campaign has failed to achieve any material health care benefits. Since 1999, there has been no overall change in the amount of pain that Americans report.³⁰

25. The National Institutes of Health (“NIH”) not only recognizes the opioid abuse problem, but also identifies Defendants’ “aggressive marketing” as a major cause: “Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*.”³¹ As shown below, the “drastic increases in the number of prescriptions written and dispensed” and the “greater social acceptability for using medications for different purposes “ are not really independent causative factors but are in fact the direct result of “the aggressive marketing by pharmaceutical companies.”

26. The rising numbers of persons addicted to opioids have led to significantly increased health care costs as well as a dramatic increase of social problems, including drug abuse and diversion³² and the commission of criminal acts to obtain opioids throughout the United States. The CDC recently estimated that the total “economic burden” of prescription opioid misuse alone in the United States is \$78.5 billion a year, including the costs of health care, lost

²⁹ FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death.

<http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm>.

³⁰ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

³¹ America’s Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed March 31, 2016) (emphasis added).

³² According to the CDC, when prescription medicines are obtained or used illegally, it is called “drug diversion.”

productivity, addiction treatment, and criminal justice involvement.³³ Consequently, public health and safety throughout the United States has been significantly and negatively impacted due to the misrepresentations and omissions by Defendants regarding the appropriate uses and risks of opioids, ultimately leading to widespread inappropriate use of the drug.

27. From 1990 to 2015 the average consumption of hydrocodone nationwide increased by 300%. In the same period, there was a 500% increase in the number of Emergency Department visits attributed to hydrocodone abuse with 19,221 visits estimated in 2000.³⁴

28. Deaths from prescription opioids have quadrupled since 1999. From 2000 to 2014 nearly half a million-people died from such overdoses. In 2015 over 33,000 Americans died as a result of an opioid overdose,³⁵ and an estimated 2 million people in the United States suffered from substance use disorders related to prescription opioid pain medicines (including fentanyl), and 591,000 suffered from a heroin use disorder (not mutually exclusive).³⁶ Prescription opioid misuse is a significant risk factor for heroin use; 80 percent of heroin users first misuse prescription opioids.³⁷

29. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors. When turned down

³³ Florence, C. S., Zhou, C., Luo, F. & Xu, L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Medical Care* 54, 901-906, doi:10.1097/MLR.0000000000000625 (2016).

³⁴ http://www.crchealth.com/addiction/drug-addiction-rehab/drug-addiction-rehab-2/home-2/hydrocodone_addiction/

³⁵ Rudd, R. A., Seth, P., David, F. & Scholl, L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. *MMWR Morb. Mortal. Wkly. Rep.* 65, 1445-1452, doi:10.15585/mmwr.mm650501e1 (2016).

³⁶ Substance Abuse and Mental Health Services Administration National Survey on Drug Use and Health 2015 Detailed Tables. (2016).

³⁷ Muhuri, P. K., Gfroerer, J. C. & Davies, M. C. (CBHSQ [Center for Behavioral Health Statistics and Quality] Data Review, 2013).

by one physician, many of these addicts deploy increasingly desperate tactics—including doctor shopping, use of aliases, and criminal means—to satisfy their cravings, cravings which Defendants first fostered then fueled.

30. Florida is currently experiencing an epidemic of opioid-related overdose and death. People with opioid addiction are at high risk of overdose and death.

31. Opioid-related deaths have been on the rise across Florida and the country at an alarming rate. In one way or another — through deaths, nonfatal overdoses, or disruptions to jobs, marriages, families, and neighborhoods — nearly every community has been impacted by this growing crisis.

32. The Defendant pharmaceutical manufactures intentionally overstated the benefits and downplayed the risks of the use of their opioids and aggressively marketed (directly and through key opinion leaders) these drugs to physicians and the Defendant distributors failed to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates as required under the Controlled Substances Act.

33. Plaintiffs and the PLR Class bring this suit against the Defendants because they have been victimized by the fraudulent and misleading scheme perpetrated by these drug manufacturers, distributors, promoters and sellers. These companies and individuals put profits ahead of patient safety and the immeasurable toll the opioid epidemic has caused throughout Florida and specifically the losses sustained by Plaintiffs and the PLR Class. Plaintiffs' Assignors and the PLR Class have paid for a substantial amount of the opioid-related health care costs including prescription, addiction and rehabilitation, overdose and alternative drug treatments incurred by their Florida Medicaid beneficiaries.

34. As a direct and foreseeable consequence of Defendants' wrongful conduct,

Plaintiffs' Assignors and the PLR Class have incurred and continue to incur costs for opioid prescriptions in excess of those they would have otherwise incurred, payments for their Medicaid beneficiary's treatment for opioid addiction, and payments for emergency hospital visits for their Medicaid beneficiaries, including payments for Naloxone Hydrochloride (Narcan) resulting from opioid abuse and overdose. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiffs' Assignors and the PLR Class. Accordingly, Plaintiffs and the PLR Class seek compensation and reimbursement for these losses, as well as potential attorneys' fees and costs, and punitive damages as allowable.³⁸

III. THE PARTIES

A. PLAINTIFFS

35. Plaintiff, MSPA CLAIMS 1, LLC, is a Florida Limited Liability Company with its principal place of business located at 5000 S.W. 75th Avenue, Suite 400, Miami, Florida 33155. At all times material, MSPA CLAIMS 1, LLC was authorized to conduct and is conducting business in Miami, Miami-Dade County, Florida.

36. MSPA CLAIMS 1, LLC, at all times materials, was and is the ultimate assignee of valid and legally binding Assignment Agreements executed by certain Plaintiffs' Assignors. A representative example of MSPA CLAIMS 1, LLC's Assignors includes, but is not limited to, Interamerican Medical Center Group, LLC and Professional Health Choice, Inc. These Assignors are all Florida entities that have contracted with and/or are licensed by AHCA to provide health care benefits and related services to Florida Medicaid beneficiaries through certain Medicaid

³⁸ Plaintiffs, collectively and on behalf of the PLR Class, hereby give notice to all parties that they intend to seek leave of court to amend this Class Action Complaint to add a prayer for punitive damages pursuant to Rule 1.190(f), Fla. R. Civ. P., and § 768.72, Fla. Stat.

managed health care plans, including, but not limited to, Coventry Health Care, Simply Health Care Plans, Inc., Amerigroup Florida, Inc. and Sunshine State Health Plan, Inc.

37. At all times material, MSPA CLAIMS 1, LLC's Assignors have irrevocably assigned their rights of reimbursement, recovery and subrogation to MSPA CLAIMS 1, LLC. Accordingly, MSPA CLAIMS 1, LLC is authorized to bring this cause of action against the Defendants.

38. Plaintiff, MAO-MSO RECOVERY II, LLC, is a Delaware Limited Liability Company with its principal place of business located at 45 Legion Drive, Cresskill, New Jersey 07626.

39. MAO-MSO RECOVERY II, LLC has established various Specific series wherein each specific Series is owned exclusively by MAO-MSO RECOVERY II, LLC. The specific Series have been designated with specific characteristics to identify the specific assignors assigning to MAO-MSO RECOVERY II, LLC. All specific Series form a part of MAO-MSO RECOVERY II, LLC and are owned by MAO-MSO RECOVERY II, LLC. MAO-MSO RECOVERY II, LLC's limited liability company agreement provides for the establishment of one or more specific Series. The records maintained for such Series account for the assets associated with such specific Series. All records of all Series are maintained together with all assets of the limited liability company. The limited liability company agreement provides that there are no limitations on liabilities of any Series. Pursuant to its limited liability agreement and applicable amendment(s), MAO-MSO RECOVERY II, LLC owns and controls any and all Series interests and all claims rights transferred from any assignor and may allocate any assets, including assignments, to a Series. MAO-MSO RECOVERY II, LLC's limited liability agreement provides that any rights and benefits arising from assignments to its series shall belong to MAO-MSO

RECOVERY II, LLC.

40. At all times material, MAO-MSO RECOVERY II, LLC was and is the ultimate assignee of valid and legally binding Assignment Agreements executed by certain Plaintiffs' Assignors. A representative example of MAO-MSO RECOVERY II, LLC's Assignors includes, but is not limited to, Preferred Medical Plan, Inc. All times relevant hereto, Preferred Medical Plan, Inc. was a Florida profit corporation that with its principal place of business located in Miami-Dade County Florida. Preferred Medical Plan, Inc. was licensed to operate and operated as a Managed Care Organization that entered into a risk contract with AHCA to provide health care benefits and related services to Florida Medicaid beneficiaries as a Medicaid managed care plan.

41. At all times material, MAO-MSO RECOVERY II, LLC's Assignors have irrevocably assigned their rights of reimbursement, recovery and subrogation to the Plaintiff, MAO-MSO RECOVERY II, LLC. Accordingly, MAO-MSO RECOVERY II, LLC is authorized to bring this cause of action against the Defendants.

42. MSP RECOVERY CLAIMS, SERIES LLC, is a Delaware entity with its principal place of business located at 5000 S.W. 75th Avenue, Suite 400, Miami, Florida 33155.

43. Plaintiff, MSP RECOVERY CLAIMS, SERIES LLC, has established various Specific series wherein each specific Series is owned exclusively by MSP RECOVERY CLAIMS, SERIES LLC. The specific Series have been designated with specific characteristics to identify the specific assignors assigning to MSP RECOVERY CLAIMS, SERIES LLC. All specific Series form a part of MSP RECOVERY CLAIMS, SERIES LLC and are owned by MSP RECOVERY CLAIMS, SERIES LLC. MSP RECOVERY CLAIMS, SERIES LLC's limited liability company agreement provides for the establishment of one or more specific Series. The records maintained

for such Series account for the assets associated with such specific Series. All records of all Series are maintained together with all assets of the limited liability company. The limited liability company agreement provides that there are no limitations on liabilities of any Series. Pursuant to its limited liability agreement and applicable amendment(s), MSP RECOVERY CLAIMS, SERIES LLC owns and controls any and all Series interests and all claims rights transferred from any assignor and may allocate any assets, including assignments, to a Series. MSP RECOVERY CLAIMS, SERIES LLC's limited liability agreement provides that any rights and benefits arising from assignments to its series shall belong to MSP RECOVERY CLAIMS, SERIES LLC.

44. At all times material, MSP RECOVERY CLAIMS, SERIES LLC was and is the ultimate assignee of valid and legally binding Assignment Agreements executed by certain Plaintiffs' Assignors. A representative example of MSP RECOVERY CLAIMS, SERIES LLC's Assignors includes, but is not limited to, Family Physicians Group, Inc., Physician Access Urgent Care Group, LLC, Trinity Physicians, LLC and veriMED IPA, LLC. These Assignors are all Florida entities that have contracted with and/or are licensed by AHCA to provide health care benefits and related services to Florida Medicaid beneficiaries through certain Medicaid managed health care plans, including, but not limited to, Coventry Health Care, Freedom Health, Inc., Simply Health Care Plans, Inc. and Humana Medical Plan.

45. At all times material, MSP RECOVERY CLAIMS, SERIES LLC's Assignors have irrevocably assigned their rights of reimbursement, recovery and subrogation to the Plaintiff, MSP RECOVERY CLAIMS, SERIES LLC. Accordingly, MSP RECOVERY CLAIMS, SERIES LLC is authorized to bring this cause of action against the Defendants.

46. At all times material to this cause of action, Plaintiffs' Assignors and the PLR Class have paid and/or provided reimbursement for some or the entire purchase price on behalf of their

Florida Medicaid beneficiaries for prescription opioids, which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants. Plaintiffs' Assignors and the PLR Class have sustained injury as a direct and proximate result of the Defendants' illegal and wrongful conduct alleged herein and seek recovery of any and all costs, damages or losses sustained as a result of the provision of care, services and/or supplies, including, but not limited to, the delivery of prescription opioid medications, treatments, hospitalizations, neonatal care, addiction and rehabilitation treatment, overdose or other opioid-related healthcare and substance abuse services.

B. DEFENDANTS

1. Manufacturer Defendants

47. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs throughout the State of Florida. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders, including, but not limited to, reporting suspicious orders to the Florida Department of Business and Professional Regulation Controlled Substance Reporting database ("CSR").

48. Defendant, ANDA, INC., is a Florida profit corporation with its principal place of business located at 2915 Weston Road, Weston, Florida 33331. At all times material, ANDA, INC., was authorized to conduct and is conducting business throughout the State of Florida, including, but not limited to, conducting business in Miami, Miami-Dade County, Florida. Service of process on Defendant, ANDA, INC., is predicated on Florida Statutes § 48.081 and § 48.091

49. ANDA, INC. is a leader in the pharmaceutical distribution industry and the 4th largest distributor of generic pharmaceuticals in the U.S. At all times material, ANDA, INC. was and is engaged in the business of distributing generic, brand, specialty and Over-the-Counter pharmaceutical products, including the Defendants' opioid prescription drugs, to retail independent and chain pharmacies, nursing homes, mail order pharmacies, hospitals, clinics and physician offices throughout the State of Florida.

50. In addition, on or about August 2016, ANDA, INC. was acquired by Defendant, TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("TEVA LTD."), an Israeli corporation. Service of process on Defendant, TEVA LTD., is predicated on Florida Statutes § 48.081 and § 48.091.

51. TEVA LTD. is a leading global pharmaceutical company and the world's largest generic medicine manufacturer. At all times material, TEVA LTD. manufactured, sold and/or distributed its generic and brand opioid prescription drugs throughout the world and the United States, including Florida.

52. As part of the acquisition deal, TEVA LTD. acquired ANDA, INC.'s distribution center located in Weston, Florida. As of the filing of this Class Action Complaint, ANDA, INC. and TEVA LTD., continue to operate and distribute generic opioid prescription drugs through their Weston, Florida distribution center.

53. At all times material, TEVA LTD. has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

54. Defendant, TEVA PHARMACEUTICALS USA, INC. ("TEVA USA"), is a Delaware corporation with its principal place of business located in North Wales, Pennsylvania. TEVA USA, at all times material, was and is authorized to conduct business in the State of Florida. Service of process on Defendant, TEVA USA, is predicated on Florida Statutes § 48.081 and §

48.091.

55. TEVA USA is a wholly owned subsidiary of TEVA LTD. At all times material, TEVA LTD. and TEVA USA, were and are engaged in the business of manufacturing, selling and/or distributing generic prescription opioids, including Hydrocodone, Oxycodone and Tramadol, throughout the United States, including Florida.

56. At all times material, TEVA USA has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

57. Defendant, CEPHALON, INC., is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. At all times material up to and including May 2016, CEPHALON, INC., was authorized to conduct business in the State of Florida. Service of process on Defendant, CEPHALON, INC., is predicated on Florida Statutes § 48.081 and § 48.091.

58. In 2011, TEVA LTD. acquired CEPHALON, INC. Defendants, TEVA LTD., TEVA USA, ANDA, INC. and CEPHALON, INC., work together to manufacture, promote, distribute and sell both brand name and generic versions of the opioids throughout the State of Florida, including the following:

Table 1. Cephalon Opioids

Drug Name	Chemical Name	Schedule
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl citrate	Schedule II

59. TEVA LTD., TEVA USA, and CEPHALON, INC. work together closely to market and sell CEPHALON, INC.'s products in the United States, including Florida.³⁹ TEVA LTD. conducts all sales and marketing activities for CEPHALON, INC. in the United States through TEVA USA and has done so since its October 2011 acquisition of CEPHALON, INC. TEVA LTD. and TEVA USA hold out Actiq and Fentora as TEVA products to the public.

³⁹ E.g., ACTIQ, <http://www.actiq.com/> (displaying logo at bottom-left).

TEVA USA sells all former CEPHALON, INC. branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with CEPHALON, INC.’s opioids, discloses that the guide was submitted by TEVA USA, and directs physicians to contact TEVA USA to report adverse events.

60. All of CEPHALON, INC.’s promotional websites, including those for Actiq and Fentora, display TEVA LTD.’s logo. TEVA LTD.’s financial reports list CEPHALON, INC.’s and TEVA USA’s sales as its own, and its year-end report for 2012 – the year immediately following the CEPHALON, INC. acquisition – attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including *inter alia* sales of Fentora®.⁴⁰

61. Through interrelated operations like these, TEVA LTD. operates in the United states and, specifically, the State of Florida through its subsidiaries TEVA USA, ANDA, INC. and CEPHALON, INC. The United States is the largest of TEVA LTD.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of TEVA USA, and CEPHALON, INC., TEVA LTD. would conduct those companies’ business in the United States itself. Upon information and belief, TEVA LTD. directs the business practices of TEVA USA, ANDA, INC. and CEPHALON, INC. and their profits inure to the benefit of TEVA LTD. as controlling shareholder.

62. At all times material, CEPHALON, INC. has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

63. Defendant, PURDUE PHARMA L.P., is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. PURDUE

⁴⁰ Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

PHARMA L.P., at all times material, was and is authorized to conduct business in the State of Florida. Service of process on Defendant, PURDUE PHARMA L.P., is predicated on Florida Statutes § 48.081 and § 48.091.

64. Defendant, PURDUE PHARMA INC., is a Delaware corporation with its principal place of business in Stamford, Connecticut. PURDUE PHARMA INC., at all times material, was and is authorized to conduct business in the State of Florida. Service of process on Defendant, PURDUE PHARMA INC., is predicated on Florida Statutes § 48.081 and § 48.091.

65. Defendant, THE PURDUE FREDERICK COMPANY, INC., is a Delaware corporation with its principal place of business in Stamford, Connecticut. Service of process on Defendant, THE PURDUE FREDERICK COMPANY, INC., is predicated on Florida Statutes § 48.081 and § 48.091.

66. Defendants, PURDUE PHARMA, L.P., PURDUE PHARMA, INC., and THE PURDUE FREDERICK COMPANY, INC. (hereinafter collectively referred to “PURDUE”), at all times material, were and are engaged in the business of manufacturing, selling and/or distributing prescription opioids, throughout the United States, including Florida. The PURDUE Defendants, at all times material, have had and continue to have substantial and not isolated contacts with Florida and are subject to the jurisdiction of Florida.

67. PURDUE manufactures, promotes, sells, and distributes opioids throughout the State of Florida, including the following:

Table 2. Purdue Opioids

Drug Name	Chemical Name	Schedule
OxyContin	Oxycodone hydrochloride extended release	Schedule II
MS Contin	Morphine sulfate extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Buprenorphine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone	Schedule II

68. OxyContin is PURDUE’s largest-selling opioid. Since 2009, PURDUE’s national

annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers).

69. Defendant, JOHNSON & JOHNSON (“J&J”) is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Service of process on Defendant, J&J, is predicated on Florida Statutes § 48.081 and § 48.091.

70. At all times material, J&J was and is engaged in the business of manufacturing, selling and/or distributing prescription opioids, throughout the United States, including Florida. Defendant, J&J, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

71. Defendant, JANSSEN PHARMACEUTICALS, INC. (“JANSSEN PHARMACEUTICALS”) is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J. Service of process on Defendant, JANSSEN PHARMACEUTICALS, is predicated on Florida Statutes § 48.081 and § 48.091.

72. JANSSEN PHARMACEUTICALS was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

73. Defendant, JANSSEN PHARMACEUTICALS, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

74. Defendant, ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (“OMP”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Service of process on Defendant, OMP, is predicated on Florida Statutes § 48.081 and § 48.091.

75. Defendant, OMP, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

76. Defendant, JANSSEN PHARMACEUTICA, INC. (“JANSSEN PHARMACEUTICA”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania

corporation with its principal place of business in Titusville, New Jersey. Service of process on Defendant, JANSSEN PHARMACEUTICA, is predicated on Florida Statutes § 48.081 and § 48.091.

77. Defendant, JANSSEN PHARMACEUTICA, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

78. NORAMCO, INC. (“NORAMCO”) is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. NORAMCO is licensed by the Pennsylvania Department of Health as a manufacturer or repackager/labeler of prescription drugs and controlled substances. Service of process on Defendant, NORAMCO, is predicated on Florida Statutes § 48.081 and § 48.091.

79. Defendant, NORAMCO, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

80. J&J is the only company that owns more than 10% of JANSSEN PHARMACEUTICALS stock. Upon information and belief, J&J controls the sale and development of JANSSEN PHARMACEUTICALS’s drugs and JANSSEN PHARMACEUTICALS’s profits inure to J&J’s benefit.

81. J&J, JANSSEN PHARMACEUTICALS, OMP, JANSSEN PHARMACEUTICA and NORMACO (collectively, “JANSSEN”) are or have been engaged in the manufacture, promotion, distribution, and sale of opioids throughout the State of Florida, including the following:

Table 3. Janssen Opioids

Drug Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II

Nucynta ⁴¹	Tapentadol extended release	Schedule II
Nucynta ER	Tapentadol	Schedule II

82. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

83. Defendant, ENDO HEALTH SOLUTIONS, INC. (“EHS”), is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Service of process on Defendant, EHS, is predicated on Florida Statutes § 48.081 and § 48.091.

84. Defendant, EHS, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

85. Defendant, ENDO PHARMACEUTICALS, INC. (“EPI”), is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Service of process on Defendant, EPI, is predicated on Florida Statutes § 48.081 and § 48.091.

86. Defendant, EPI, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

87. EHS and EPI (collectively, “ENDO”) manufacture, promote, distribute and sell opioids throughout the State of Florida, including the following:

Table 4. Endo Opioids

Drug Name	Chemical Name	Schedule
Opana ER	Oxymorphone hydrochloride extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II

⁴¹ Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

88. Opioids made up roughly \$403 million of ENDO's overall revenues of \$3 billion in 2012. Opana ER yielded revenue of \$1.15 billion from 2010 to 2013, and it accounted for 10% of ENDO's total revenue in 2012.

89. Defendant, QUALITEST PHARMACEUTICALS, INC. ("QUALITEST"), is a wholly owned subsidiary of ENDO and is an Alabama corporation with its principal place of business in Huntsville, Alabama. Service of process on Defendant, QUALITEST, is predicated on Florida Statutes § 48.081 and § 48.091.

90. Defendant, QUALITEST, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida

91. ENDO manufactures and sells generic opioids, both directly and through its subsidiary, Defendant, QUALITEST, including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

92. Defendant, ALLERGAN PLC f/k/a ACTAVIS, PLC. ("ALLERGAN"), is a diversified global pharmaceutical company with its principal place of business in the United States located in Parsippany, New Jersey. Service of process on Defendant, ALLERGAN, is predicated on Florida Statutes § 48.081 and § 48.091.

93. Defendant, ALLERGAN, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

94. Defendant, WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS INC. acquired Actavis, Inc. in October of 2012. The combined company adopted the name ACTAVIS, INC. as of January 2013 before finally settling on ACTAVIS PLC in October 2013 with its principal place of business located in Parsippany, New Jersey. Service of process on Defendant, ACTAVIS PLC, is predicated on Florida Statutes § 48.081 and § 48.091.

95. Defendant, ACTAVIS PLC, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

96. WATSON LABORATORIES, INC. is a Nevada Corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of ALLERGAN (f/k/a

Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Service of process on Defendant, WATSON LABORATORIES, INC., is predicated on Florida Statutes § 48.081 and § 48.091.

97. Defendant, WATSON LABORATORIES, INC., at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

98. ACTAVIS PHARMA, INC (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. Service of process on Defendant, ACTAVIS PHARMA, INC., is predicated on Florida Statutes § 48.081 and § 48.091.

99. Defendant, ACTAVIS PHARMA, INC., at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

100. Defendant, ACTAVIS, LLC, is a Delaware Limited Liability Company with its principal place of business in Parsippany, New Jersey. At all times material, ACTAVIS, LLC, was authorized to conduct and conducted business in the State of Florida. Service of process on Defendant, ACTAVIS, LLC, is predicated on Florida Statutes § 48.081 and § 48.091.

101. Defendant, ACTAVIS, LLC, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

102. Defendants, ALLERGAN PLC, ACTAVIS PLC, ACTAVIS INC., ACTAVIS LLC, ACTAVIS PHARMA INC., WATSON PHARMACEUTICALS, INC., WATSON PHARMA INC., and WATSON LABORATORIES, INC., are collectively referred to as "ACTAVIS."

103. ACTAVIS manufactures, promotes, sells and distributes prescription opioids, throughout the State of Florida, including the following:

Table 5. Actavis Opioids

Drug Name	Chemical Name	Schedule
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Kadian ⁴²	Morphine sulfate	Schedule II
Norco	Hydrocodone and acetaminophen	Schedule II
Generic versions of Duragesic	Fentanyl	Schedule II
Generic versions of Opana	Oxymorphone hydrochloride	Schedule II

104. Defendant, MALLINCKRODT PLC, is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Service of Process on Defendant, MALLINCKRODT PLC, is predicated on Florida Statutes § 48.081 and § 48.091.

105. MALLINCKRODT LLC is a limited liability company organized and existing under the laws of the State of Delaware, and is registered with the New York Secretary of State to do business in New York. Service of Process on Defendant, MALLINCKRODT LLC, is predicated on Florida Statutes § 48.081 and § 48.091.

106. Since 2013, MALLINCKRODT LLC has been a wholly owned subsidiary of MALLINCKRODT PLC. Prior to 2013, MALLINCKRODT LLC was a wholly-owned subsidiary of the Irish public limited company Covidien PLLC (formerly known as Tyco Healthcare). Defendants, MALLINCKRODT PLC and MALLINCKRODT LLC, are referred to as “MALLINCKRODT.” At all times material, Defendants MALLINCKRODT had and continue to have substantial and not isolated contacts with Florida and are subject to the jurisdiction of Florida.

107. MALLINCKRODT manufactures, markets, and sells prescription opioid drugs throughout the State of Florida, including generic oxycodone. MALLINCKRODT is one of the largest manufacturers of generic oxycodone and opioids sold since at least June 2009 under the

⁴² ACTAVIS acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009

brand names Exalgo (hydromorphone), Xartemis (oxycodone/acetaminophen) and Roxicodone (oxycodone) (known by the street names “M,” “roxies/roxys” or “blues”). In July 2017 MALLINCKRODT agreed to pay \$35 million to settle allegations brought by the United States Department of Justice that it failed to detect and notify the Drug Enforcement Agency (“DEA”) of suspicious orders of controlled substances.

2. Distributor Defendants

108. The Distributor Defendants also are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Distributors universally failed to comply with federal and/or state law, including, but not limited to reporting suspicious orders to the CSR. The Distributor Defendants are engaged in “wholesale distribution,” as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Distributors is responsible for the volume of prescription opioids plaguing the United States And its territories.

109. Defendant, MCKESSON CORPORATION (“MCKESSON”), is a Delaware corporation with its principal place of business in San Francisco, California. At all times material, MCKESSON was authorized to conduct and conducted business in the State of Florida. Service of Process on Defendant, MCKESSON, is predicated on Florida Statutes § 48.081 and § 48.091.

110. Defendant, MCKESSON, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

111. For fiscal year ended March 31, 2017, MCKESSON generated revenues of \$198.5 Billion.

112. In its 2017 Annual Report, MCKESSON stated that it “partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the

right patients at the right time, safely and cost-effectively.”⁴³

113. According to the 2017 Annual Report, MCKESSON’s “pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico.”⁴⁴

114. MCKESSON is the largest pharmaceutical distributor in the United States.

115. MCKESSON does substantial pharmaceutical business in Florida and has more than 40,000 customers nationally. At all times material up to and including December 2016, MCKESSON owned and operated a prescription drug distribution center, including the distribution of opioid prescription drugs, in Lakeland, Florida.

116. Defendant, CARDINAL HEALTH INC. (“CARDINAL”), is an Ohio corporation with its principal place of business in Dublin, Ohio. At all times material, CARDINAL was authorized to conduct and conducted business in the State of Florida. Service of Process on Defendant, CARDINAL, is predicated on Florida Statutes § 48.081 and § 48.091.

117. Defendant, CARDINAL, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

118. In 2016, CARDINAL generated revenues of \$121.5 billion.

119. CARDINAL does substantial pharmaceutical business in Florida. At all times material, CARDINAL owned and operated a prescription drug distribution center, including the distribution of opioid prescription drugs, in Lakeland, Florida.

120. Defendant, AMERISOURCEBERGEN DRUG CORPORATION (“AMERISOURCEBERGEN”), is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. At all times material, AMERISOURCEBERGEN was authorized to conduct and conducted business in the State of Florida. Service of Process on Defendant,

⁴³ McKesson 2017 Annual Report found at:

investor.mckesson.com/sites/mckesson.investorhq.businesswire.com/files/report/file/2017_McKesson_A.

⁴⁴ *Id.*

AMERISOURCEBERGEN, is predicated on Florida Statutes § 48.081 and § 48.091.

121. Defendant, AMERISOURCEBERGEN, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida.

122. According to its 2016 Annual Report, AMERISOURCEBERGEN is “one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care.”⁴⁵

123. AMERISOURCEBERGEN does substantial pharmaceutical business in Florida. At all times material, AMERISOURCEBERGEN owned and operated a prescription drug distribution center, including the distribution of opioid prescription drugs, in Orlando, Florida.

124. Defendant, ABBOTT LABORATORIES, INC. (“ABBOTT”), is a Delaware corporation with its principal place of business in Abbott Park, Illinois. Service of Process on Defendant, ABBOTT, is predicated on Florida Statutes § 48.081 and § 48.091.

125. Defendant, ABBOTT, at all times material, has had and continues to have substantial and not isolated contacts with Florida and is subject to the jurisdiction of Florida

126. ABBOTT was primarily engaged in the promotion and distribution of opioids throughout the United States, including Florida, due to a co-promotional agreement with Defendant PURDUE. Pursuant to that agreement, between 1996 and 2006, ABBOTT actively promoted, marketed, and distributed PURDUE’s opioid products as set forth above.

127. ABBOTT, as part of the co-promotional agreement, helped make OxyContin into the largest selling Opioid in the nation. Under the co-promotional agreement with PURDUE, the more ABBOTT generated in sales, the higher the reward. Specifically, ABBOTT received 25% to 30% of all net sales for prescriptions written by doctors its sales force called on. This agreement

⁴⁵ Amerisource 2016 Annual Report found at:
<http://www.amerisourcebergen.com/investor/phoenix.zhtml?c=61181&p=irol-irhome>

was in operation from 1996-2002, following which ABBOTT continued to receive a residual payment of 6% of net sales up through at least 2006.

128. With ABBOTT's help, sales of OxyContin went from a mere \$49 million in its first full year on the market to \$1.6 billion in 2002. Over the life of the co-promotional agreement, PURDUE paid ABBOTT nearly half a billion dollars.

129. In 2007, PURDUE settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States \$635 million. At the time, this was one of the largest settlements with a drug company for marketing misconduct.

130. Defendants, ANDA, INC., MCKESSON, CARDINAL, ABBOTT and AMERISOURCEBERGEN (collectively "Distributor Defendants") are the largest opioid distributors in the United States and its territories.

131. The Distributor Defendants purchased opioids from manufacturers, such as the Pharmaceutical Defendants, and sold them to, among others, retail independent and chain pharmacies, hospitals, clinics, and physician offices throughout the State of Florida, which in turn sold them and were paid for by Plaintiffs' Assignors and the PLR Class.

132. The Distributor Defendants played an integral role in distributing opioids to Florida Medicaid beneficiaries.

133. The Distributor Defendants owe a duty under federal law (21 USCA §823, 21 CFR 1301.74) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids. In addition, effective July 2011, the Distributor Defendants were required to submit monthly controlled substance distribution reports to the CSR pursuant to Florida Statute § 499.0121.

134. Pursuant to the Florida Statute § 499.0121, "Storage and handling of prescription drugs, recordkeeping", also known in its entirety as the "Drug, Cosmetic and Household Product Act", "[t]he department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare."

135. Section 499.0121(6) of this statute is entitled "recordkeeping." It requires that

wholesale distributors “maintain inventories and records” of all transactions regarding the receipt and distribution of prescription drugs. § 499.0121(6)(1), Fla. Stat. It also requires that wholesale distributors that deal in controlled substances, such as the defendants herein, “comply with all applicable state, local and federal laws.”

136. Pursuant to Florida Statute § 499.021(11), titled “Distribution Reporting,” wholesale distributors are required to submit a report to the department of its receipts and distributions of controlled substances, shall report all transactions of controlled substances. This data must then be shared with the “Department of Law Enforcement and local law enforcement agencies upon request and must monitor purchasing to identify levels that are inconsistent with the purchasing entity’s clinical needs.”

137. Pursuant to § 499.021(15), Fla. Stat., titled “Due Diligence of Purchasers,” wholesale distributors, such as the Defendants, “must establish and maintain policies and procedures to credential physicians...and pharmacies that purchase or otherwise receive from the wholesale distributor controlled substances...” Furthermore, they must “maintain records of such credentialing and make the records available to the department upon request.” This section requires that such credentialing include, among other things, “a determination that the receiving entity’s Schedule II and Schedule II controlled substance purchasing history, if any, is consistent with and reasonable for that entity’s clinical business needs.” § 499.021(15)(a)(3), Fla. Stat.

138. Pursuant to Florida Statute § 499.021(15)(b):

A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. A wholesale distributor must assess orders for greater than 5,000 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. In making such assessments, a wholesale distributor may consider the purchasing entity’s clinical business needs, location, and population served, in addition to other factors established in the distributor’s policies and procedures. A wholesale distributor must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon

method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. The wholesale distributor shall maintain records that document the report submitted to the department in compliance with this paragraph.

139. The Defendants were each on notice that the controlled substances they manufactured and distributed were the kinds that were susceptible to diversion for illegal purposes, abused, overused, and otherwise sought for illegal, unhealthy and problematic purposes.

140. The Defendants were each on notice that there was an alarming and suspicious rise in manufacturing and distributing opioids to retailers throughout the State of Florida during this time period.

141. As entities involved in the manufacture and distribution of opioid medications, Defendants were engaged in abnormally and/or inherently dangerous activity and had a duty of care under Florida.

142. The Defendants had a duty to notice suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies including the DEA and the Florida Department of Health.

143. The Defendants knew or should have known that they were supplying vast amounts of dangerous drugs throughout Florida that were already facing abuse, diversion, misuse, and other problems associated with the opioid epidemic.

144. Between 2007 through 2016, the Distributor Defendants shipped millions of doses of highly addictive controlled opioid pain killers into and throughout Florida.

145. According to the Drug Enforcement Administration Automation of Reports and Consolidated Orders System ("ARCOS"), from 2007 to 2016 pharmaceutical distributors, including Defendants, distributed amounts of opioid pain medications, such as oxycodone and

hydrocodone, into and throughout Florida that represented suspicious and alarming numbers

146. The Distributor Defendants failed in their duty to take action to prevent or reduce the distribution of these drugs.

147. The Distributor Defendants were in a unique position and had a duty to monitor, report, or otherwise limit the flow of these drugs throughout the State of Florida.

148. The Distributor Defendants were warned in 2006 and 2007 by the DEA about their responsibility to avoid filling suspicious orders.

149. The Distributor Defendants, in the interest of their own massive profits, intentionally failed in this duty.

150. The DEA has repeatedly taken administrative action to enforce compliance:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against AMERISOURCEBERGEN's Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AMERISOURCEBERGEN entered into a settlement which resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the CARDINAL's Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against CARDINAL's Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against CARDINAL's Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against CARDINAL's Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, MCKESSON entered into an Administrative

Memorandum of Agreement (“2008 MOA”) with the DEA which provided that MCKESSON would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 CFR §1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;

- g. On September 30, 2008, CARDINAL entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that CARDINAL failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia; Valencia, California; and Denver, Colorado;
- h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against CARDINAL’s Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, CARDINAL agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center;
- j. On January 5, 2017, MCKESSON entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA, as well as failure to identify and report suspicious orders at its facilities in Aurora, CO, Aurora, IL, Delran, NJ, LaCrosse, WI., Lakeland, FL, Landover, MD, LaVista, NE, Livonia, MI, Metheun, MA, Santa Fe Springs, CA, Washington Courthouse, OH, and West Sacramento, CA.; and
- k. In Florida, the DEA found that MCKESSON failed to report pharmacy orders for hydromorphone that dramatically exceed historical sales levels originating from its Lakeland, Florida distribution center.⁴⁶ As a result, the Lakeland distribution center is barred from selling hydromorphone products for one (1) year as part of the agreement. *Id.*

151. The Distributor Defendants are members of the Healthcare Distribution Management Association (“HDMA”). The HDMA created “Industry Compliance Guidelines,” which stressed the critical role of each member of the supply chain in distributing controlled

⁴⁶ <http://www.modernhealthcare.com/article/20170117/NEWS/170119908>.

substances. The HDMA guidelines provided that “[a]t the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers.”

152. The extraordinary increase in the volume of opioid pain medications distributed to nationwide retailers should have put the Distributor Defendants on notice to investigate and report such orders.

153. The Distributor Defendants delivered an excessive and unreasonable amount of opioid pain medications to retailers throughout the United States, including Florida, which was a proximate cause of Plaintiffs’ Assignors and PLR Class paying for inappropriate opioid prescriptions.

154. The Distributor Defendants knew or should have known that they were distributing levels of opioid medications that far exceeded the legitimate needs of Medicaid beneficiaries and other users throughout the United States, including Florida.

155. The Distributor Defendants paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications.

156. The Distributor Defendants made substantial profits from the opioids paid for by Plaintiffs’ Assignors and PLR Class.

157. By the actions and inactions described above, the Distributor Defendants showed a reckless disregard for the safety of Medicaid beneficiaries and other users throughout the State of Florida.

3. Key Opinion Leaders (“KOLs”)

158. Russell Portenoy, M.D., is an individual residing in New York. Defendant Portenoy is a physician licensed to practice medicine in the State of New York. Dr. Portenoy was instrumental in promoting opioids for sale and distribution nationally and in the State of Florida.

159. Perry Fine, M.D., is an individual residing in Utah. Dr. Fine was instrumental in promoting opioids for sale and distribution nationally and in the State of Florida.

160. Scott Fishman, M.D., is an individual residing in California. Dr. Fishman was

instrumental in promoting opioids for sale and distribution nationally and in the State of Florida.

161. Lynn Webster, M.D., is an individual residing in Utah. Dr. Fine was instrumental in promoting opioids for sale and distribution nationally and in the State of Florida.

IV. JURISDICTION AND VENUE

162. This is a Class Action Complaint brought pursuant to Rule 1.220, Fla. R. Civ. P., in which the damages at issue exceed Fifteen Thousand Dollars (\$15,000.00), exclusive of interest, costs and any attorneys' fees.

163. At all times material to this cause of action:

- a. Greater than two-thirds of the Plaintiffs' Assignors and members of the PLR Class in the aggregate were and are citizens of the State of Florida;
- b. Defendant, ANDA, INC., from whom significant relief is sought and who's tortious conduct alleged herein forms a significant basis for the claims asserted by Plaintiffs and the PLR Class, is a Florida corporation and otherwise deemed a citizen of this state;
- c. The principal injuries, losses or damages sustained by the Plaintiffs' Assignors and PLR Class as a result of the intentional and tortious conduct alleged herein were incurred in Florida; and
- d. Two-thirds or more of the Plaintiffs' Assignors and members of the PLR Class in the aggregate, and Defendant, ANDA, INC., are citizens of the State of Florida.

164. This Court has personal jurisdiction over the Defendant opioid manufacturers, distributors and key opinion leaders in this case pursuant to § 48.193(1)(a) and (2), Florida Statutes.

165. At all times material to this cause of action, the Defendants, individually or acting by and through their agents, officers and representatives, operated, conducted, engaged in or carried on a business venture in Florida; maintained an office or agency in this state; solicited business or provided service activities within this state; engaged in substantial and not isolated activity within this state; and/or committed a tortious act within the state by, among other things:

- a. Manufacturing, selling and distributing highly addictive prescription opioid

drugs in Florida while engaging in a pattern and practice of disseminating patently false and misleading information about the safety and efficacy of these opioid drugs;

- b. Intentionally diminishing the associated health hazards of prescription opioid drugs and conspiring with key opinion leaders to increase their sales and profits despite the known risks and dangerous propensity of these drugs;
- c. Consensually submitting to the jurisdiction of Florida when obtaining a manufacturer or distributor license; and/or
- d. Owning and/or operating a distribution center in Florida that distributes the Defendant manufacturers' prescription opioid drugs to the citizens of Florida, including Florida Medicaid beneficiaries.

166. Defendants' intentional and tortious conduct is continuing and presently existing, arose out of or is incidental to each Defendant's interstate, intrastate and international business ventures conducted in the United States, including Florida, and proximately caused the Plaintiffs' Assignors and PLR Class to sustain losses and damages in the State of Florida.

167. Accordingly, the Defendants have the requisite minimum contacts with Florida necessary to constitutionally permit this Court to exercise jurisdiction because:

- a. The Defendants' contacts with Florida, including, but not limited to, their manufacture, sale, distribution and/or promotion of highly addictive prescription opioid drugs, are directly related to and gave rise to this Class Action Complaint;
- b. Defendants' purposefully availed themselves of the privilege of conducting business in the State of Florida by selling, distributing and/or promoting the use of highly addictive prescription opioid drugs to doctors, hospitals, patients, health insurers and other individuals throughout the State of Florida; and
- c. Defendants' fraudulent and deceptive marketing campaign and intentional misconduct was such that the Defendants should have reasonably anticipated being hauled into court in Florida.

See § 48.913, Fla. Stat.

168. This Court has subject matter jurisdiction under Florida Statute § 501.201, et seq.,

for violation of FDUPTA and under Florida Statute §§ 895.03 and 895.05 based upon Plaintiffs' Florida Civil RICO claims, as well over the remaining Florida law claims alleged herein.

169. Venue is proper in Miami-Dade County, Florida pursuant to §§ 47.021 and 47.051, Florida Statutes, inasmuch as several Defendants, including, without limitation, ANDA, INC., TEVA USA, PURDUE, MCKESSON, CARDINAL and AMERISOURCEBERGEN, have and/or usually keep offices for transaction of their customary business in Miami-Dade County, Florida and/or have an agent or other representative in Miami-Dade County, Florida.

170. Venue is also proper in Miami-Dade County, Florida pursuant to § 47.051, Florida Statutes, because all or a substantial part of the cause of action accrued in Miami-Dade County, Florida, inasmuch as the Defendants tortious conduct occurred in this county and the Plaintiffs' Assignors, as well as a substantial number of the PLR Class, paid for and sustained damages or losses as a result of the provision of care, services and/or supplies, including, but not limited to, the delivery of the Defendants' prescription opioid medications, treatments, hospitalizations, neonatal care, addiction and rehabilitation treatment, overdose or other opioid-related healthcare and substance abuse services to Medicaid beneficiaries in Miami-Dade County, Florida.

171. All purported conditions precedent to the filing of this Class Action Complaint have occurred or have been performed.

V. STANDING

A. MEDICAID AND THIRD-PARTY LIABILITY

172. In 1965, Congress established the Medicaid Program as a joint federal-state medical assistance program authorized by Title XIX of the Social Security Act ("the Act"), 42 U.S.C. § 1396, et seq., and regulations promulgated thereunder (hereinafter referred to as "Medicaid" or "Medicaid Program"). The Children's Health Insurance Program ("CHIP") was established in 1997 to provide new coverage opportunities for children in families with incomes too high to

qualify for Medicaid, but who could not afford private coverage. Both Medicaid and CHIP are administered by states within broad federal guidelines and jointly funded by the federal government and states.

173. The Medicaid Program provides for payment for medical items or services, or both, on behalf of eligible low-income adults, children, pregnant women, elderly adults and people with disabilities that is administered by the Centers for Medicare and Medicaid Services (“CMS”) and single state agencies that administer or supervise the administration of the state Medicaid plan under federal law. *See* 42 CFR Parts 431, 433, 438, 440, 457 and 495. In Florida, Medicaid and CHIP are administered by AHCA pursuant to Florida Statute § 409.901, et seq.

174. Under the Medicaid Program, each state that chooses to participate in the program and receive federal financial participation for program expenditures, establishes eligibility standards, benefits packages, and payment rates, and undertakes program administration pursuant to the applicable federal statutory and regulatory standards. *Id.* Although states are not required to participate in Medicaid, all of them do.⁴⁷

175. Similarly, even though pharmacy coverage is an optional benefit under the Medicaid Program pursuant to Section 1905(a)(12) of the Act, all states currently provide coverage for outpatient prescription drugs to all eligible individuals within the their state Medicaid Programs.⁴⁸ The Medicaid prescription drug programs include the management, development and administration of systems and data collection necessary to operate the Medicaid Drug Rebate program as authorized by Section 1927 of the Act.

⁴⁷ *See Moore ex rel. Moore v. Reese*, 637 F.3d 1220, 1232 (11th Cir. 2011); *see also, Arkansas Department of Health and Human Services v. Ahlborn*, 547 U.S. 268, 126 S.Ct. 1752, 164 L.Ed.2d 459 (2006) (describing the structure and administration of the Medicaid Program).

⁴⁸ *See* <https://www.medicaid.gov/medicaid/prescription-drugs/index.html>.

176. In general, in order for payment to be made available under section 1903 of the Act for covered outpatient drugs, manufacturers must enter into a Medicaid Drug Rebate program as set forth in section 1927(a) of the Act. Section 1927 of the Act provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, and requirements for states for covered outpatient drugs. Pursuant to such rebate agreements, drug manufacturers agree to make rebate payments⁴⁹ to each state Medicaid agency for the Manufacturer's Covered Outpatient Drugs paid for by the state Medicaid agency during a quarter.⁵⁰

177. As such, state Medicaid agencies typically pay for any FDA-approved drug that the physician prescribes for an FDA-approved indication that are prescribed on either an in-patient or out-patient basis. Like Medicare, federal law *mandates* that state expenditures for prescription drugs may *only* be made for claims for FDA-approved drugs.

178. Moreover, as a condition of participating in the Medicaid program, states must comply with the third-party liability provisions set forth under 42 U.S.C. § 1396a(a)(25) and assignment provisions set forth under 42 U.S.C. § 1396k(a).

179. Under this federal scheme, Medicaid is intended to be the “payor of last resort.” *See* Federal Register, Vol. 81, No. 88, 27498 through 27901, 27769 (May 6, 2016). Title XIX of the Act requires state Medicaid agencies to identify and seek payment from liable third parties, before billing Medicaid.

⁴⁹ *See* § 1927(c)(1)(B)(the required rebate rate is 23.1%).

⁵⁰ *See* § 1927(b)(3)(B)(the Secretary of the U.S. Department of Health and Human Services may impose a civil monetary penalty up to \$100,000 for each item, on a wholesaler, manufacturer, or direct seller of a Covered Outpatient Drug, if a wholesaler, manufacturer or direct seller of a Covered Outpatient Drug refuses a request for information about charges or prices by the Secretary in connection with a survey *or* knowingly provides false information).

180. Pursuant to the federal third-party liability provisions, states are required to “take all reasonable measures to ascertain the legal liability of third parties ... to pay for care and services available under the [State’s Medicaid] plan.” 42 U.S.C. § 1396a(a)(25)(A). If third-party liability is found after the State has provided medical services to a beneficiary and “the amount of reimbursement the state can reasonably expect to recover exceeds the costs of such recovery,” the State is required to “seek reimbursement ... to the extent of such legal liability.” 42 U.S.C. § 1396a(a)(25)(B). That provision further specifies that a third party is any individual, entity, or program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under a State plan.

181. In addition, states must require Medicaid beneficiaries to assign to the State their rights to seek and collect payment for medical care from a responsible third party. 42 U.S.C. § 1396k(a)(1)(A) (a State plan for medical assistance shall “provide that, as a condition of eligibility for medical assistance under the State plan to an individual who has the legal capacity to execute an assignment for himself, the individual is required to assign the State any rights, of the individual ... to payment for medical care from any third party”); 42 U.S.C. § 1396a(a)(25)(H) (“to the extent that payment has been made under the State plan for medical assistance in any case where a third party has a legal liability to make payment for such assistance, the State has in effect laws under which, to the extent that payment has been made under the State plan for medical assistance for health care items or services furnished to an individual, the State is considered to have acquired the rights of such individual to payment by any other party for such health care items or services”). *See also* 42 C.F.R. § 433.137–433.154.

182. Until the early 1990’s, the majority of Medicaid benefits were provided to Medicaid beneficiaries through fee-for-service arrangements directly administered by the state Medicaid

agencies. *See* Federal Register, Vol. 81, No. 88, at 27500. However, over time that practice changed and state Medicaid agencies began to contract with various types of Managed Care Organizations (“MCO’s”), Pre-Paid Inpatient Health Plans (“PIHP’s”), Pre-Paid Ambulatory Health Plans (“PAHP’s”) and Primary Care Case Managers (“PCCM”), for the delivery of Medicaid health care benefits and additional services through a health care delivery system organized to manage cost, utilization and quality. *Id.* at 27500. Under these contracts, the MCO’s accept a fixed, prospective amount, per member per month (capitation) payment for these services.⁵¹

183. The state Medicaid agencies are authorized to implement a Medicaid managed care delivery system under four types of federal authorities: (a) State plan amendment authorizing states to implement a mandatory managed care delivery system pursuant to Section 1932(a) of the Act; (b) Waiver authority pursuant to Section 1915(a) of the Act, which allows states to implement a voluntary managed care program by executing a contract with organizations that the state has procured through a competitive procurement process. Currently, thirteen states (and Puerto Rico) use 1915(a) contracts to administer twenty-four voluntary managed care plans; (c) Waiver authority pursuant to Section 1915(b) of the Act, which allows states to require all Medicaid beneficiaries to enroll in a managed care delivery system through one of four 1915(b) waivers; and (d) Waiver authority pursuant to Section 1115 of the Act, which allows states to enroll all Medicaid beneficiaries in a managed care delivery system as part of experimental, pilot or demonstration projects.

⁵¹ “Capitation payment” means a payment the State makes periodically to a contractor on behalf of each beneficiary enrolled under a contract based on the actuarially sound capitation rate for the provision of services under the State plan. The State makes the payment regardless of whether the particular beneficiary receives services during the period covered by the payment. *See* 42 CFR § 438.2.

184. By way of example, in 1992, 2.4 million Medicaid beneficiaries (or 8% of all Medicaid beneficiaries) were enrolled in some type of Medicaid managed care plan. By July 1, 2014, that number had exponentially increased to more than 55 million Medicaid beneficiaries (or 77% of all Medicaid beneficiaries) that accessed part or all of their Medicaid benefits through some type of Medicaid managed care plan.⁵²

185. The MCO's, in turn, provide these Medicaid health care benefits and additional services to Medicaid beneficiaries through a network providers or subcontractors. A "network provider" means any provider⁵³, group of providers or entity that has a network provider agreement with an MCO, PIHP, or PAHP, or a subcontractor, and receives Medicaid funding directly or indirectly to order, refer or render covered services as a result of the state's contract with an MCO, PIHP, or PAHP. *See* 42 CFR § 438.2. A "subcontractor" means an individual or entity that has a contract with an MCO, PIHP, PAHP, or PCCM entity that relates directly or indirectly to the performance of the MCO's, PIHP's, PAHP's, or PCCM entity's obligations under its contract with the State. *Id.*

186. The Medicaid MCO's, PIHP's or PAHP's, are authorized to delegate their responsibilities of providing health care benefits and services to Medicaid beneficiaries under their risk contracts with the state Medicaid agency, subject to the requirements and limitations set forth in 42 CFR § 438.20, be entering into risk contracts with Providers or Subcontractors, including, but, not limited to, first tier, downstream and related entities ("FDR entities").⁵⁴ The standards set

⁵² 2014 Medicaid Managed Care Enrollment Report. <https://www.medicaid.gov/medicaid/managed-care/enrollment/index.html>.

⁵³ "Provider" means any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is legally authorized to do so by the State in which it delivers the services. *See* 42 CFR § 438.2.

⁵⁴ "First tier" entity means any party that enters into a written arrangement, acceptable to CMS, with an MA organization or applicant to provide administrative services or health care services for a Medicare eligible

forth in § 438.20 were modeled on the Medicare Advantage (“MA”) standards relating to MA organization relationships with FDR entities set forth in 42 CFR § 422.504(i).⁵⁵

187. The Providers or Subcontractors, including, but, not limited to, FDR entities, bear the full risk of loss pursuant to their contractual relationships with the Medicaid MCO's, PIHP's or PAHP's. FDR entities, include Management Service Organizations (“MSO’s”) and Independent Physician Associations (“IPA’s”).

188. These Medicaid MCO’s and Providers or Subcontractors, including, but, not limited to, FDR entities, stand in the same shoes as their contracted state Medicaid agencies to provide Medicaid health care benefits and additional services to Medicaid beneficiaries, including, but not limited to, the same responsibilities, limitations and the same rights and responsibilities of pursuing third-party liability claims when delegated that authority pursuant to the applicable state law or by contract.

189. CMS published guidance in 2012 on Medicaid.gov affirming that Medicaid MCO’s should be treated as if they were the state Medicaid agency when the State has delegated responsibility and authority to perform third-party liability functions to the MCO’s. *See* Federal Register, Vol. 81, No. 88, at 27771. The contract language between the state Medicaid agency and the Medicaid MCO’s, or where applicable specific state law, dictate the terms and conditions under which the MCO’s assume third-party liability responsibility.⁵⁶

individual under the MA program. “Downstream entity” means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit, below the level of the arrangement between an MA organization (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. *See* 42 CFR § 422.2, Fla. Stat.

⁵⁵ *See* Federal Register, Vol. 81, No. 88, at 27598.

⁵⁶ *See* Medicaid Third Party Liability and Coordination of Benefits.

<https://medicaid.gov/medicaid/eligibility/tpl-cob/index.html>; Coordination of Benefits and Third-Party Liability (COB/TPL) Training and Handbook in Medicaid 2016.

<https://www.medicare.gov/medicaid/eligibility/downloads/tpl-cob/training-and-handbook.pdf>.

190. Specifically, when MCO's seek to recover third-party liability benefits, the MCO can seek to recover:

- a. The Medicaid fee schedule amount for the service furnished;
- b. The full amount the insurer is legally liable to pay for the service;
- c. The amount the MCO allows for the service;
- d. The amount the provider bills for the service; or
- e. The monthly capitation payment for the service.

See id. at 51 – 53.

191. Accordingly, various types of Medicaid MCO's have the statutory and contractual right to pursue and recover third-party liability claims as required by the applicable federal third-party liability provisions set forth under 42 U.S.C. § 1396a(a)(25) and assignment provisions set forth under 42 U.S.C. § 1396k(a).

B. FLORIDA'S STATEWIDE MEDICAID MANAGED CARE PROGRAM

192. In Florida, the Medicaid Program is administered by AHCA pursuant to § 409.901, Florida Statutes, et seq. (hereinafter referred to as "Florida Medicaid" or "Florida Medicaid Program"). Florida has offered Medicaid services since 1970 to eligible children, seniors, disabled adults and pregnant women. Florida Medicaid reimburses for covered drugs dispensed by an approved Florida Medicaid pharmacy provider, or a provider enrolled as a dispensing practitioner, in accordance with the provisions of 42 CFR § 447, Subpart I.

193. Since approximately 2006, Florida Medicaid beneficiaries participated in a managed care demonstration program called the Florida Medicaid Pilot under a Section 1115(a) Waiver (Medicaid demonstration waivers). The pilot program was initiated in two counties in 2006 and expanded to three more counties by 2007. In December 2011, Florida expanded the pilot

program in all counties.

194. Part IV of Chapter 409, Florida Statutes §§ 409.961 – 409.985, established Florida’s statewide, integrated managed care program for all covered services, including long-term care services, referred to as Statewide Medicaid Managed Care (“SMMC”). *See* § 409.964, Fla. Stat. Contracted managed care plans participate in one, or both, of two SMMC risk-based programs: one for managed medical assistance (“MMA”) (Section 1115(a) Waiver) and one for long-term care (“LTC”) (operating under the authority of combined Section 1915(b) and (c) Waivers) through a capitated MCO. *See e.g.* §§ 409.973 and 409.98, Fla. Stat. (list of services to be provided by MMA and LTC plans, respectively). Additionally, some managed care plans in the MMA program provide services to specialty populations who meet specified criteria based on age, condition or diagnosis.

195. In order to qualify as a managed care plan or MCO under the SMMC, an entity must be a dully licensed Health Maintenance Organization (“HMO”), Provider Service Network (“PSN”), Exclusive Provider Organization (“EPO”), Accountable Care Organization (“ACO”) or other insurer. *See* § 409.962(7), Fla. Stat. Moreover, under the Section 1115(a) Waiver, MCO’s must meet a medical loss ratio standard, which requires them to spend at least 85% of total premiums received on activities directly related to the provision of care.⁵⁷ As of 2011, AHCA contracted with two dozen MCO’s to provide services under the two risk-based programs.

196. Between 2013 and 2014, the Florida Medicaid Program initiated a major shift toward the use of a mandatory managed health care delivery system that pays plans based on established capitation rates. This new program made Medicaid managed care enrollment

⁵⁷ *See e.g.*, § 409.967(4), Fla. Stat.; *see also*, <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/managed-care/downloads/florida-mcp.pdf>.

mandatory on a statewide basis effective October 1, 2014.⁵⁸ See § 409.971, Fla. Stat. For example, Preferred Medical Plan, Inc., all times relevant up to and including December 2015, was a dully qualified MMA managed care plan that participated in the SMMC program by providing health care benefits and services to Florida Medicaid beneficiaries enrolled in its program.⁵⁹

197. By August 2016, approximately 82% of Florida's Medicaid beneficiaries were enrolled in an MMA or LTC risk-based program.

198. In January 2018, Florida had enrolled 3,852,683 individuals in the Florida Medicaid Program.⁶⁰ This represents a net increase of over 16% since the first Marketplace Open Enrollment Period and related changes to Medicaid were enacted in October 2013. Of these enrollees, approximately 3,102,714 individuals were enrolled in some type of SMMC program. See *id.*

199. Participating MCO's in the SMMC program are paid a capitated rate under a risk contract. The capitation rate is defined as the "per-member, per-month payment" that is paid by AHCA to an MCO for each Medicaid beneficiary enrolled under a risk contract for the provision of Medicaid services during the payment period. See §§ 409.962(13) and 409.968(1), Fla. Stat. The MCO is required to accept the capitation payment received each month as payment in full by AHCA for all services provided to enrollees covered under the risk contract; in addition to, the administrative costs incurred by the MCO in providing or arranging for such services.

200. Any and all costs incurred by the MCO in excess of the capitation payment shall be borne in total by the MCO. The capitation payment "shall be risk-adjusted rates based on historical

⁵⁸ The only groups that remain exempt from mandatory managed care enrollment are women who are eligible only for family planning services, women eligible through the breast and cervical cancer services program, and people who are eligible for emergency Medicaid for aliens. See § 409.965, Fla. Stat.

⁵⁹ Plaintiff, MAO-MSO RECOVERY II, LLC, is the ultimate assignee of valid and legally binding Assignment Agreement executed by Preferred Medical Plan, Inc.

⁶⁰ AHCA Current Comprehensive Medicaid Managed Care Enrollment Report (January 2018). http://www.fdhc.state.fl.us/Medicaid/Finance/data_analytics/enrollment_report/index.shtml

utilization and spending data, projected forward, and adjusted to reflect the eligibility category, geographic area, and clinical risk profile of the recipients.” § 409.968(1), Fla. Stat. Accordingly, costs incurred by the MCO above and beyond the capitated payment amount in a given calendar year is not recouped by the MCO and, instead, become a loss to the MCO. Similarly, to the extent that the prospective risk-adjusted rates are insufficient to cover the continuing increased costs incurred by the MCO for the delivery of health care benefits and related services to their Medicaid enrollees, those losses are also permanent and ongoing.

201. The MCO’s, like their MA counterparts, are authorized to delegate their responsibilities of providing health care benefits and services to Florida Medicaid beneficiaries under their risk contracts with AHCA, subject to certain requirements and limitations, by entering into risk contracts with Medicaid Providers, including, but, not limited to, FDR entities.⁶¹

202. Pursuant to Florida Statute § 409.910, the Medicaid Third-Party Liability Act, the Florida Legislature intended that Florida Medicaid be the “payor of last resort” for medically necessary good and services provided to Florida Medicaid beneficiaries. The Medicaid Third-Party Liability Act, provides, in pertinent part, that “[t]hird-party benefits for medical services shall be primary to medical assistance provided by Medicaid [and] [a]fter the agency has provided medical assistance under the Medicaid program, it shall seek reimbursement from third-party benefits to the limit of legal liability and for the full amount of third-party benefits.”⁶² See § 409.910(3) and (4), Fla. Stat.

⁶¹ A “Medicaid provider” or “Provider” means a person or entity that has a Medicaid provider agreement in effect with AHCA and is in good standing with AHCA. § 409.901(17), Fla. Stat. A “Medicaid provider agreement” means a contract between AHCA and a provider for the provision of services, or both, to Medicaid recipients pursuant to Medicaid. § 409.901(18), Fla. Stat.

⁶² “Third party” means any individual, entity or program, excluding Medicaid, that is, may be, could be, should be, or has been liable for all or part of the cost of medical services related to any medical assistance covered by Medicaid. § 409.901(27), Fla. Stat.

203. Plaintiffs' Assignors and members of the putative PLR Class have the unique position of being "payors of last resort" in that they stand in the same shoes as AHCA. They entered into risk contracts with AHCA as a Medicaid MCO and/or were licensed by AHCA to provide health care benefits and related services to Florida Medicaid beneficiaries through risk contracts with a Medicaid MCO to provide such services. Under a risk contract, the MCO or Medicaid Provider receives a monthly capitated payment and assumes the risk for the costs associated with providing health care benefits and services to Florida Medicaid beneficiaries enrolled in a managed care plan and further assumes the risk of incurring loss if the costs of furnishing these services exceed the payments under the contract. *See* 42 CFR § 438.2.

204. Plaintiffs' Assignors and the PLR Class were ultimately forced to pay for and absorb the losses related to the delivery of care, services and/or supplies, including, the delivery of prescription opioid medications, treatments, hospitalizations, addiction and rehabilitation treatment, overdose or other opioid-related health care services to their respective Florida Medicaid beneficiaries that vastly exceeded the capitated payments they received for these enrollees. Accordingly, Plaintiffs and the PLR Class are entitled to seek recovery for these losses and damages sustained as a direct and proximate result of the Defendants' intentional and tortious acts and/or omissions as "payors of last resort."

C. PLAINTIFFS' RIGHTS UNDER THEIR ASSIGNMENT AGREEMENTS

1. Plaintiffs' Valid and Binding Assignment Agreements

205. Plaintiffs have entered into valid and binding Assignment Agreements with certain Medicaid MCO's and Providers, including, but not limited to, MCO's, PIHP's, PAHP's, HMO's, MSO's, PSN's, EPO's, ACO's, PCCM, IPA's, and FDR Entities, that contracted with and/or were licensed by AHCA to provide health care benefits and related services to Florida Medicaid beneficiaries.

206. Plaintiffs' Assignors have irrevocably assigned all of their rights of recovery, reimbursement and subrogation to the Plaintiffs, as the ultimate assignees of the Assignment Agreements. The Plaintiffs' Assignors entered into risk-based contracts in exchange for capitated payments with AHCA and/or entered into risk contracts with MCO's to provide the health care benefits and services to enrollees under the MCO's risk contract with AHCA. Accordingly, Plaintiffs' Assignors have standing to bring the causes of action set forth herein, including, but not limited to, the responsibility and authority to perform third-party liability functions and/or are authorized to perform such functions pursuant to Florida law.

207. Plaintiffs own all of the Assignors' claims for recovery and reimbursement, as well as their subrogation rights, including the right to pursue recovery of medical claims or payments, amounts owed on unpaid bills, and expenses paid by Assignors on behalf of their Medicaid beneficiaries, from third-party liability entities or from entities liable as primary payers, including the Defendants.

208. The underlying Assignment Agreements, alleged in some detail below, assigned all legal rights of reimbursement and recovery, as well as subrogation rights, for the recovery of payments for the health care and services paid by the Plaintiffs' Assignors on behalf of their Medicaid beneficiaries; whether said rights arise from (i) contractual agreements between the MCO and AHCA; (ii) contractual agreements between the MCO and Medicaid Providers under the risk contract between the MCO and AHCA; (iii) state and federal laws that delegate the responsibility and authority to the MCO's to perform third-party liability recovery activities; and/or (iv) all other applicable federal or state laws.

209. The Assignment Agreements for each of these transactions will be produced to the Defendants subject to their execution of an appropriate Protective Order, so as not to disclose the

business terms between each Plaintiff and its assignors, and other confidential and proprietary business information, including trade secrets.

210. Each assignor that provides coverage for Florida Medicaid beneficiaries has paid one or more claims for the beneficiaries as a result of the Defendants' wrongful conduct entitling the Plaintiffs to seek the recovery and reimbursements sought herein. Upon obtaining the proper HIPAA compliant documentation from the Defendants so as to protect PHI (Protected Health Information), the Defendants will be provided with all patient names and claims data.

2. Representative Assignment Agreement with Preferred Medical Plan, Inc., a Florida MCO/HMO and Participating MMA Plan

211. Preferred Medical Plan, Inc. ("PMPI"), at all times material up to and including December 2015, owned and operated an MCO/HMO located in Miami-Dade County, Florida. PMPI entered into an MMA risk contract in exchange for capitated payments with AHCA for the provision of health care benefits and services to Florida Medicaid beneficiaries enrolled in PMPI's Medicaid managed care plan within the SMMC program. PMPI paid for and absorbed the losses related to the delivery of opioid-related health care services provided to Florida Medicaid beneficiaries enrolled in its managed care plan and such costs and losses vastly exceeded the capitated payments PMPI received from AHCA for these enrollees.

212. On May 3, 2016, PMPI entered into a Recovery Agreement with MSP Recovery, LLC, a Florida limited liability company and/or its assigns, wherein it assigned its right of recovery, reimbursement and subrogation to MSP Recovery, LLC (hereinafter referred to as the "PMPI Assignment Agreement"). The PMPI Assignment Agreement provides, in pertinent part, as follows:

WHEREAS, [PMPI] is a Health Maintenance Organization, Maintenance Service Organization, Independent Practice Association, Medical Center, and/or other health care organization and/or provider and is duly authorized

by state or federal law, and/or other administrative or licensing agencies to provide or arrange for the provision of medical and health care services and/or supplies including medications, treatment or other procedures ("health care services") to persons, who are covered under government healthcare programs such as Medicare, Medicaid or Medicare Advantage as well as Commercial Lines of business; and

WHEREAS, [PMPI] has certain legal rights to recover payments for the provision of health care services arising from contractual agreements, such as participation and network agreements with applicable capitation and risk sharing arrangements, and state and federal laws that provide for the reimbursement of conditional payments and/or any other payments made by [PMPI]...

WHEREAS, [PMPI] wishes to engage MSP Recovery to analyze, identify, pursue, and collect claims recovery on its behalf.

213. Pursuant to Article I, § 1.1 – MSP Recovery's Services, of the PMPI Assignment Agreement, MSP Recovery, LLC contractually agreed to do the following:

Upon receipt of [PMPI's] claims data, MSP Recovery shall conduct a review and analysis of the data and use its best efforts to identify claims for which [PMPI] has a legal right of recovery and reimbursement. **In accordance with the assignment of claims provision herein, all claims that have been or can be identified by MSP Recovery as being recoverable by [PMPI] pursuant to the Medicare Secondary Payer Act or any other contractual, statutory, equitable or legal basis, whether state or federal, and whether arising as a Part A, B or D claim(s), and/or as a result of payments made for or on behalf of a Medicaid beneficiary or as a result of any payment(s) made through any health plan, shall be deemed Assigned Claims**, as defined herein. As part of its services and recovery efforts, MSP Recovery will determine the available primary insurance coverage and/or other responsible parties for secured and unsecured claims and pursue those claims accordingly. It is the intent of the parties that all claims are hereby assigned.

MSP Recovery shall initiate and pursue the recovery of the Assigned Claims and, for every potential recoverable amount of Assigned Claims, MSP Recovery shall use commercially reasonable efforts to recover the value of the Assigned Claims for which [PMPI] has a right to recover.

(Emphasis added).

214. Further, PMPI irrevocably assigned its rights of recovery, reimbursement and

subrogation to MSP Recovery, LLC under Article III, § 3.1 – Assigned Claims, of the PMPI

Assignment Agreement:

[PMPI] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any all of [PMPI's] right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for [PMPI] that [PMPI] had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to [PMPI] arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims"... This assignment is irrevocable and absolute.

215. On August 8, 2016, MSP Recovery, LLC entered into an Assignment and Sale of Claims and Rights to Proceeds with Plaintiff, MAO-MSO RECOVERY II, LLC, pursuant to the authority and terms as set forth in Article I, § 1.1, of the PMPI Assignment Agreement:

In order to offer its services more efficiently, MSP Recovery shall pursue the recovery and reimbursement of the **Assigned Claims** in its own name or in the name of an affiliated entity. Accordingly, MSP Recovery may assign this Agreement to any affiliated entity.

216. As set forth in the August 8, 2016 Assignment and Sale of Claims and Rights to Proceeds, MSP Recovery, LLC irrevocably assigned all of its legal and equitable rights arising from the PMPI Assignment Agreement to Plaintiff, MAO-MSO RECOVERY II, LLC:

WHEREAS, Assignor [MSP Recovery Services, LLC] has acquired, and in the future may acquire, from Preferred Medical Plan Inc., a Florida Corporation (collectively with its affiliates, "HMO"), all legal and equitable rights, entitlements, claims and causes of action of HMO to recover payments and/or claims paid by or on behalf of HMO with respect to healthcare services and/or supplies, including but not limited to the "Claims" and "Assigned Claims", as such terms are defined in the Recovery Agreement ("Recovery Agreement") dated as of May 3, 2016, by and between Assignor and HMO (all such legal and equitable rights, entitlements, claims and causes of action, and proceeds and products thereof, collectively, the "Assigned Claims").

Assignor [MSP Recovery Services, LLC] hereby irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee [MAO-MSO Recovery II, LLC] and its successors and assigns, all of Assignor's right, title, ownership and interest in and to all Assigned Claims, plus all proceeds, products and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the Assigned Claims, and all rights and claims against primary payers and/or third parties that may be liable to Assignor arising from or relating to the Assigned Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims".

217. Pursuant to the August 8, 2016 Assignment and Sale of Claims and Rights to Proceeds, Plaintiff, MAO-MSO RECOVERY II, LLC, is the ultimate assignee, owns all rights arising from the PMPI Assignment Agreement and, therefore, has legal standing to bring the instant cause of action against the Defendant opioid manufacturers, distributors and key opinion leaders.

3. Representative Assignment Agreement with Interamerican Medical Center Group, LLC, a Florida Medicaid Provider and MSO/IPA

218. Interamerican Medical Center Group, LLC ("IMC"), at all times material to this cause of action, owns and operates an MSO and/or IPA located in Miami-Dade County, Florida. IMC is an AHCA licensed Medicaid Provider that is authorized to provide health care benefits and services to Florida Medicaid beneficiaries enrolled in various MMA plans within the SMMC program. IMC, in turn, entered into risk contracts with various Medicaid MCO's, including, but not limited to, Coventry Health Care of Florida and Simply Health Care Plans, Inc., to provide such Medicaid services and benefits as required under the MCO's risk contract with AHCA. As such, IMC paid for and absorbed the losses related to the delivery of opioid-related health care services provided to Florida Medicaid beneficiaries assigned to its health care clinics and such

costs and losses vastly exceeded the capitated payments IMC received for these enrollees.

219. On December 16, 2014, IMC entered into an Assignment Agreement with MSP Recovery, LLC, a Florida limited liability company, wherein it irrevocably assigned its right of recovery, reimbursement and subrogation to MSP Recovery, LLC (hereinafter referred to as the “IMC Assignment Agreement”). The IMC Assignment Agreement, provides, in pertinent part, as follows:

WHEREAS, [IMC] operates a Health Maintenance Organization(s), MSO(s), Medical Center(s), and/or is a Physician, and/or, otherwise, has the right by state, federal, other proper licensing, and/or other administrative agency or agencies to provide care, services, and/or supplies including Medications. Therefore, [IMC] provides and/or arranges Emergency, managed healthcare to and for the benefit of insureds otherwise known as Medicare and/or **Medicaid Beneficiaries through an MA/MMA**, or as the assignee of those rights and/or obligations. The parties hereto understand and are otherwise aware that **some or all of [IMC’s] rights may derive from legal and/or equitable rights determined by its contractual agreements(s), which include but are not limited to the following: i) capitation agreements, ii) full risk agreements**, and/or iii) other rights, and/or obligations pursuant to state laws, federal laws of any type, and/or nature whatsoever as well as the legal and/or equitable nature of [IMC’s] claim(s) that have been paid and/or where there is the possibility that a conditional payment may be made.

By way of this Agreement, [IMC] appoints, directs, and, otherwise, **irrevocably assigns** all of [IMC’s] rights as it pertains to the rights pursuant to any plan, State or Federal statute(s) whatsoever directly and/or indirectly for any of its members and/or plan participants and/or its rights pursuant to any agreement... [to MSP Recovery].

(Emphasis added).

220. Pursuant to Article I, § 1.1 – Contractor Relationship, of the IMC Assignment Agreement, MSP Recovery, LLC contractually agreed to recover, among other things, any costs, claims, damages or losses sustained by IMC, arising out of:

Any claim involving intentional tort(s), negligent commission(s), negligent omission(s), and/or product liability claim(s) for which a member has

received Medical treatment paid for by [IMC] and/or otherwise incurred pursuant to contract, state, or federal laws; and any and all medical care treatments, diagnostics, and/or supplies that a member received and/or can receive that can be collected from any source that is primarily responsible as Medicare and/or **Medicaid are payors of last resort.**

(Emphasis added).

221. On February 20, 2015, MSP Recovery, LLC entered into an Assignment of Claims and Causes of Action with Plaintiff, MSPA CLAIMS 1, LLC, a Florida limited liability company. Pursuant to the February 20, 2015 Assignment Agreement, MSP Recovery, LLC irrevocably assigned all of its legal and equitable rights arising from the IMC Assignment Agreement to Plaintiff, MSPA CLAIMS 1, LLC:

WHEREAS, pursuant to a contract entered into between IMC, LLC and [MSP Recovery, LLC], copies of which are attached hereto as Exhibits A, Assignor is the assignee of the claims, rights and causes of action set forth in such contracts (the "Assigned Claims").

Assignor [MSP Recovery, LLC] hereby irrevocably assigns, transfers, conveys, sets over, and delivers to Assignee [MSPA Claims 1, LLC] or its assigns any and all of Assignor's right, title, ownership and interest in and to all rights and entitlements, that Assignor has, may have had, or has asserted against third parties arising from or relating to the Claims.

222. Pursuant to the February 20, 2015 Assignment of Claims and Causes of Action, Plaintiff, MSPA CLAIMS 1, LLC, is the ultimate assignee, owns all rights arising from the IMC Assignment Agreement and, therefore, has legal standing to bring the instant cause of action against the Defendant opioid manufacturers, distributors and key opinion leaders.

4. Representative Assignment Agreement with Trinity Physicians, LLC, a Florida Medicaid Provider and MSO

223. Trinity Physicians, LLC ("TPS"), at all times material to this cause of action, owns and operates an MSO located in Hillsborough County, Florida. TPS is an AHCA licensed

Medicaid Provider that is authorized to provide health care benefits and services to Florida Medicaid beneficiaries enrolled in various MMA plans within the SMMC program. TPS, in turn, entered into risk contracts with various Medicaid MCO's, including, but not limited to, Freedom Health, Inc. and Humana Medical Plan, to provide such Medicaid services and benefits as required under the MCO's risk contract with AHCA. As such, TPS paid for and absorbed the losses related to the delivery of opioid-related health care services provided to Florida Medicaid beneficiaries assigned to its health care clinics and such costs and losses vastly exceeded the capitated payments TPS received for these enrollees.

224. On November 3, 2015, TPS entered into a Health Care Claim(s) Cost Recovery Agreement with MSP Recovery 15-592, LLC, a Delaware limited liability company and/or its assigns, wherein it assigned its right of recovery, reimbursement and subrogation to MSP Recovery 15-592, LLC (hereinafter referred to as the "TPS Assignment Agreement"). The TPS Assignment Agreement provides, in pertinent part, as follows:

WHEREAS, [TPS] operates an MSO and its contracted physician and physicians groups are duly authorized by state, federal law, other proper licensing, and/or other administrative agency or agencies to provide or arrange for the provision of care, services, and/or supplies including medications, treatments or other procedures ("Health Care Services") to persons, who are covered under government healthcare programs (i.e., Medicare and Medicaid) and other third party; and

WHEREAS, The parties acknowledge that some or all of [TPS's] rights to payments for the provision of Health Care Services may derive from legal and/or equitable rights determined by its contractual agreement(s), which include but are not limited to: i) capitation agreements, ii) full risk agreements, and/or iii) other rights, and/or obligations pursuant to state laws, federal laws of any type, and/or nature whatsoever as well as the legal and/or equitable nature of [TPS's] claim(s) that have been paid and/or where there is the possibility that a conditional payment maybe made.

225. TPS irrevocably assigned its rights of recovery, reimbursement and subrogation to MSP Recovery 15-592, LLC under Article I, § 1.1 – Irrevocable and Absolute Assignment of

Claims, of the TPS Assignment Agreement:

[TPS] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, or its assigns, in perpetuity, any and all of [TPS's] right, title, ownership and interest in and to all rights and entitlements, and all information and data used to pursue and/or recover monies for [TPS] that [TPS] has, may have had, or has asserted against any party (the "Assigned Claims"). This includes, but is not limited to, primary payors and/or third parties that may be liable to [TPS] arising from or relating to the Assigned Claims.

226. Further, pursuant to Article III, § 3.1 – MSP Recovery's Obligations, Representations, Investigation and Costs, of the TPS Assignment Agreement, MSP Recovery 15-592, LLC contractually agreed to do the following:

For every potential recoverable amount of the Assigned Claims, MSP Recovery, in its sole discretion, will use commercially reasonable efforts to recover amounts of the Assigned Claims to which [TPS] has a right to recover pursuant to the MSP Act and other contractual or equitable grounds available to [TPS]. MSP Recovery will determine the available primary insurance coverage for secured and unsecured claims and pursue those claims accordingly.

227. On June 12, 2017, MSP Recovery 15-592, LLC entered into an Assignment Agreement with Plaintiff, MSP RECOVERY CLAIMS, SERIES LLC, pursuant to the authority and terms as set forth in Article IV, § 6.14 – Assignment, of the TPS Assignment Agreement, which provides: "MSP Recovery may assign the Agreement and its rights hereunder to any successor or an affiliate."

228. Accordingly, MSP Recovery 15-592, LLC irrevocably assigned all of its legal and equitable rights arising from the TPS Assignment Agreement to Plaintiff, MSP RECOVERY CLAIMS, SERIES LLC. Pursuant to the June 12, 2017 Assignment Agreement, Plaintiff, MSP RECOVERY CLAIMS, SERIES LLC, is the ultimate assignee, owns all rights arising from the TPS Assignment Agreement and, therefore, has legal standing to bring the instant cause of action against the Defendant opioid manufacturers, distributors and key opinion leaders.

229. Each of the Plaintiffs have entered into the same or similar assignment agreements with other Florida Medicaid MCO's and Providers. As a result, Plaintiffs are legally authorized and have standing to seek recovery of any and all costs, damages or loss, including, but not limited to, any subrogation and/or reimbursement claims and/or any other claims that may be brought by Plaintiffs' assignors in equity or under the applicable Florida law, related to the provision of care, services and/or supplies including the delivery of prescription opioid medications, treatments, hospitalizations, addiction and rehabilitation treatment, overdose or other opioid-related health-care services throughout the State of Florida, pertaining to any and all claims of any nature originating from a Florida Medicaid Beneficiary.

230. Based on the foregoing, Plaintiffs have standing to recover damages incurred as result of Defendants' actions and omissions. Plaintiffs have standing to bring claims pled herein, *inter alia*, to bring claims under Florida Statute § 501.201, et seq., for violation of FDUPTA and under Florida Statute § 895.03 based upon Plaintiffs' Florida Civil RICO claims, as well as for the remaining Florida law claims alleged herein.

VI. FACTS RELEVANT TO ALL CAUSES OF ACTION

A. THE PAIN-RELIEVING AND ADDICTIVE PROPERTIES OF OPIOIDS

231. The pain-relieving properties of opium have been recognized for millennia, so has the magnitude of its potential for abuse and addiction. Opioids are related to illegal drugs like opium and heroin.

232. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain – particularly on the battlefield – and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages. By 1900, an estimated

300,000 people were addicted to opioids in the United States,⁶³ and many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

233. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.

234. Studies and articles from the 1970s and 1980s also made clear the reasons to avoid opioids. Scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

235. To take advantage of the lucrative market for chronic pain patients, each defendant developed a well-funded marketing scheme based on deception. Each defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long term opioid use. Such statements benefitted not only themselves and the third-parties who gained legitimacy when

⁶³ Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

Defendants repeated those statements, but also other Defendants and opioid manufacturers. These statements were not only unsupported by, or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations.

236. Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects, caused deceptive materials and information to be placed into the marketplace, including to prescribers, patients, and third-party payors nationwide and in this District. These promotional messages were intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

237. Doctors are the gatekeepers for all prescription drugs so, not surprisingly, Defendants focused the bulk of their marketing efforts, and their multi-million-dollar budgets, on the professional medical community. Particularly because of barriers to prescribing opioids, which are regulated as controlled substances, Defendants knew doctors would not treat patients with common chronic pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks. Accordingly, Defendants did not disclose to prescribers, patients, TPP's, or the public that evidence in support of their promotional claims was inconclusive, non-existent or unavailable. Rather, each Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. As a result, doctors nationwide and in this District, began prescribing opioids long-term to treat chronic pain – something that most never would have considered prior to Defendants' campaign.

238. Drug company marketing materially impacts doctors' prescribing behavior.⁶⁴

Doctors rely on drug companies to provide them with truthful information about the risks and benefits of their products, and they are influenced by their patients' requests for particular drugs and payors' willingness to pay for those drugs.

239. Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.⁶⁵ These results are directly due to Defendants' fraudulent marketing campaign.

240. As described in detail below, Defendants:

- a. misrepresented the truth about how opioids lead to addiction;
- b. misrepresented that opioids improve function;
- c. misrepresented that addiction risk can be managed;
- d. misled doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"
- e. falsely claimed that withdrawal is simply managed;

⁶⁴ See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); see also A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

⁶⁵ Research Letter, Prescription Drug Abuse: A National Survey of Primary Care Physicians, JAMA Intern. Med. (Dec. 8, 2014), E1-E3.

- f. misrepresented that increased doses pose no significant additional risks;
- g. falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

241. Defendants' misrepresentations were aimed at doctors, patients, and third-party payors.

242. Underlying each of Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Defendants' collective effort to hide from the medical community the fact that there exist no adequate and well-controlled studies of opioid use longer than 12 weeks.⁶⁶

B. DEFENDANTS USED MULTIPLE AVENUES TO DISSEMINATE THEIR FALSE AND DECEPTIVE STATEMENTS ABOUT OPIOIDS

243. Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the country and in this District. Defendants deployed throughout the state seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain.

244. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each defendant conducted and continue to conduct advertising campaigns touting the purported benefit of their branded drugs. For example, Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The amount included \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

245. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding

⁶⁶ See note 18.

jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Arkansas.

246. Second, each Defendant promoted the use of opioids for chronic pain through "detailers"- sales representatives who visited individual doctors and medical staff in their offices and small group speaker programs. Defendants have not corrected this misinformation. Instead, each Defendant has devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes \$1 08 million spent by Purdue, \$34 million by Janssen, \$13 million by Cephalon on, \$10 million by Endo, and \$2 million by Actavis.

247. Defendants' detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed ... promotional materials that ... omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of opioids" and, specifically, the risk that "Opioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

1. Defendants Trivialized the Risks of Long Term and Higher Dosage Opioid Therapy

248. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain,

and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

249. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction to which he has become accustomed – up to and including doses that are “frighteningly high.”⁶⁷ At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

250. Opioids vary by duration. Long-acting opioids, such as Purdue’s OxyContin and MS Contin, Janssen’s Nucynta ER and Duragesic, Endo’s Opana ER, and Actavis’s Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon’s Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address “episodic pain” and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

251. Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic pain.

252. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the “grave risks” of opioids, including “addiction, overdose, and even death.” The FDA further warned, “[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death.” Because of those grave risks, the FDA said that long-acting or extended release opioids “should be used only when alternative treatments are inadequate.”⁶⁸ The FDA

⁶⁷ M. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

⁶⁸ See note 18, *supra*.

required that – going forward – opioid makers of long-acting formulations clearly communicate these risks in their labels.

253. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.⁶⁹

254. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants in the 1990s when their deceptive marketing began.

255. Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients build up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

- a. Actavis' predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options a Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an Opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.

⁶⁹ FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death.

<http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm>.

- c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that Opioid dosages may be increased until "you are on the right dose of medication for your pain."
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was recently available on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased You won't 'run out' of pain relief."
- e. Janssen sponsored a patient education guide entitled *Finding Relief Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased Opioid dosages.
- f. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage or opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high Opioid dosages. This publication is still available online.
- h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," *see* www.cpdd.org, challenging the correlation between Opioid dosage and overdose.

256. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death

at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

257. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

258. Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.⁷⁰

259. More specifically, Defendants have made misleading claims about the ability of their so-called abuse deterrent Opioid formulations to deter abuse. For example, Endo's advertisement for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal, or intravenous abuse." The FDA has subsequently taken the extraordinary action of "request[ing] that Endo Pharmaceuticals remove ... Opana ER ... from the market."⁷¹

260. According to the FDA, Endo's reformulation of Opana ER "made things worse": "[P]ostmarketing data ... demonstrate[s] a significant shift in the route of abuse of Opana ER from

⁷⁰ Catherine S. Hwang et al., Prescription Drug Abuse: A National Survey of Primary Care Physicians, 75(2) JAMA Intern. Med. 302-04 (Dec. 8, 2014)

⁷¹ Maggie Fox, *FDA Asks Drug Company to Pull its Opioid Opana Because of Abuse*, NBCNews.com (June 9, 2017), <http://www.nbcnews.com/storyline/americas-heroin-epidemic/fda-asks-drug-company-pull-its-opioid-opana-because-abuse-n770121>

nasal to injection following the product's reformulation.'" Moreover, Endo's own studies, which it fails to disclose, showed that Opana ER could still be ground and chewed.

261. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found these statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies - even when they work - "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."

262. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

263. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular Opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to connect Defendants' prior misrepresentations about the risks and benefits of opioids.

264. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, Defendants purchase, manipulate, and analyze some of the most

sophisticated data available in *any* industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, Defendants *know* their detailing to doctors is effective.

265. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term Opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations - which are described below - reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could be easily weaned from the drugs; (3) the use of higher Opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

266. Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and deceptive claims are described below:

- a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed Opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis' acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative Opioid prescriptions from multiple sources, or theft. This publication is still available online.
- c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the Opioid medications that are prescribed for them."
- d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."
- f. Janssen currently runs a website, Prescriberresponsibly.com (last updated July 2, 2015), which claims that concerns about Opioid addiction are "overestimated."
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* - which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction." This publication is still available Online.
- h. Detailers for Purdue/Abbott, Endo, Janssen, and Cephalon throughout the country and in the state of Florida and in this District or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse deterrent formulations; and routinely did not correct the misrepresentations noted above.

267. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for Opioid addiction])." The Guideline points out that "Opioid pain medication

use presents serious risks, including ... opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases the risk for opioid use disorder."

268. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term Opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-Opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

269. The warnings on Defendants' own FDA-approved drug labels caution that opioids "expose users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids.

270. The State of New York, in a 2016 settlement agreement with Endo, found that Opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State found that Endo

had no evidence for that statement.⁷² Consistent with this, Endo agreed not to "make statements that ... opioids are generally non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in other states including Florida.

271. Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants have called this phenomenon "pseudoaddiction"- a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue - and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

- a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online. The 2012 edition, which also remains available online, continues to falsely teach that pseudoaddiction is real.
- b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "[P]seudoaddiction ... refers to patient behaviors that may occur when pain is undertreated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."
- c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing*

⁷² See *Endo Health Solutions Inc.*, Assurance of Discontinuance, at 6 (N.Y. Att. Gen. Mar. 1, 2016).

Abuse, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of "[drug-seeking behaviors] in patients who have pain that has not been effectively treated."

- e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting Opioid.

272. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that Opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer term use," and that physicians should "reassess pain and function within 1 month" in order to decide whether to "minimize the risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

273. Defendants employed the same marketing plans and strategies and deployed the same message throughout the United States and its territories as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels - including detailing visits, speaker events, and advertising -and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

274. Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker

slide decks, and sales training materials; and nationally coordinated advertising. Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to check on both their performance and compliance.

2. Defendants Used a Diverse Group of Seemingly Independent Third Parties to Spread False and Deceptive Statements about the Risks and Benefits of Opioids

275. Defendants also deceptively marketed opioids through unbranded advertising - *i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third-parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

276. Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like cigarette makers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superiority of opioids to treat chronic pain. Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same

language and format to disseminate the same deceptive messages regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated nationwide, including prescribers and patients in this District.

277. Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	Opana ER Advertisement (Branded)
"People who take opioids as prescribed usually do not become addicted."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use."

a. Key Opinion Leaders ("KOLs")

278. Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

279. Defendants paid KOLs to serve as consultants on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-Opioid message, even in activities that were not directly funded by Defendants.

280. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic Opioid therapy. Defendants have created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic Opioid therapy.

281. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, and on the boards of pro-Opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to direct and exercise control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

282. Pro-Opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term Opioid use. Defendants knew that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic Opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.⁷³

283. Thus, even though some of the KOLs have recently moderated or conceded the lack

⁷³ See *In re Purdue Pharma L.P.*, Assurance of Discontinuance, 18, at 8 (N.Y. Att. Gen. Aug. 19, 2015) ("[T]he website failed to disclose that from 2008 to 2013, Purdue made payments totaling almost \$231,000, for speaker programs, advisory meetings, and travel costs, to 11 of the Advocates whose testimonials appeared on the site.").

of evidence for many of the claims they made, these admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide and throughout the State of Florida in Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

284. Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

(1) Russell Portenoy

285. Dr. Russell Portenoy, former chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and the Purdue/Abbott cabal.

286. In 1986, Dr. Russell Portenoy published an article reporting that “[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.”⁷⁴

287. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a

⁷⁴ R. Portenoy & K. Foley, Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases, 25(2) Pain 171 (1986).

*problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*⁷⁵

According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”⁷⁶

288. For all the reasons outlined by Dr. Portenoy, and in the words of one researcher from the University of Washington in 2012, and quoted by a Harvard researcher the same year, “it did not enter [doctors’] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids, because if there were any, we almost never saw them.”⁷⁷

289. Despite his writings in 1994, Dr. Portenoy was instrumental in opening the door for regular use of opioids to treat chronic pain. He served on the American Pain Society (“APS”) American Academy of Pain Medicine (“AAPM”) Guideline Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation (“APF”), an advocacy organization almost entirely funded by Defendants.

290. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-

⁷⁵ R. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

⁷⁶ *Id.*

⁷⁷ J. Loeser, Five crises in pain management, Pain Clinical Updates. 2012;20 (1):1–4(cited by I. Kissin, Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?, 6 J. Pain Research 513, 514 (2013)).

term to treat chronic pain. On this widely-watched program, broadcast in New York and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."⁷⁸

291. To his credit, Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."⁷⁹ Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, ... I guess I did."⁸⁰

(2) Lynn Webster

292. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was president in 2013 and is a current board member of AAPM, a front group that ardently supports chronic Opioid therapy. He is Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was

⁷⁸ *Good Morning America Television Broadcast*, ABC News (Aug. 30, 2010).

⁷⁹ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012.

⁸⁰ *Id.*

receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

293. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of Opioid overdoses.

294. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

295. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patients' Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors across the country including in Florida.

296. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should not be seen as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response." Endo

distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."⁸¹

b. Front Groups

297. Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic Opioid therapy. They also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit Opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

298. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure that the Groups would generate only the messages Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members -whether patients suffering from pain or doctors treating those patients.

299. Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG").

⁸¹John Fauber, Networking Fuels Painkiller Boom, Bangor Daily News.

(1) American Pain Foundation ("APF")

300. The most prominent of Defendants' Front Groups was APF, which received more than \$10 million in funding from Opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at \$1.7 million.

301. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes- including death- among returning soldiers. APF also engaged in a significant multimedia campaign - through radio, television, and the internet - to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Florida consumers, physicians, patients, and TPP's.

302. In addition to Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue), Russell Portenoy, and Scott Fishman (a KOL from the University of California, Davis who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue), all of whom served on APF's board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

303. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

304. APF held itself out as an independent patient advocacy organization. It often

engaged in grassroots lobbying against various legislative initiatives that might limit Opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2011, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

305. In practice, APF operated in close collaboration with Opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund those activities and publications, knowing that drug companies would support projects conceived as a result of those communications.

306. APF assisted in other marketing projects for drug companies. One project funded by another drug company-*AP F Reporter's Guide: Covering Pain and Its Management* (2009) recycled text that was originally created as part of the company's training document.

307. The same drug company made general grants, but even then, it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medication generally, the company representative responded, "I provided an advocacy grant to APF this year - this would be a very good issue on which to use some of that. How does that work?"

308. The close relationship between APF and the drug company highlighted in the previous paragraph was not unique, but mirrors relationships between APF and Defendants. APF's clear lack of independence - in its finances, management, and mission - and its willingness to allow Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

309. Indeed the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of

Opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

(2) American Academy of Pain Medicine ("AAPM")

310. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic Opioid therapy.

311. AAPM received over \$2.2 million in funding since 2009 from Opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event - its annual meeting held in Palm Springs, California, or other resort locations. AAPM described the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon, and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

312. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids- 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of

teaching that "the risks of addiction are ... small and can be managed."⁸²

313. AAPM's staff understood they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

314. In addition, treatment guidelines have been particularly important in securing acceptance for chronic Opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

315. In 1997, AAPM and the American Pain Society jointly issues a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.

316. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

317. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic

⁸² Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>.

pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache and Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in nationwide and in Florida during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

318. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

319. Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term Opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

320. PCF is comprised of representatives from opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (including AAPM, APS, and American Society of Pain Educators); patient advocacy groups (including APF and American Chronic Pain Association ("ACPA")); and other like-minded organizations, almost all of which received substantial funding from Defendants.

321. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA

mandated in 2009 to communicate the risks of opioids to prescribers and patients.⁸³ This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would undermine Defendants' marketing efforts. The recommendations claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, not undermine, their deceptive marketing of opioids for chronic pain.

C. OPIOID THERAPY MAKES PATIENTS SICKER WITHOUT LONG TERM BENEFITS

322. There is no scientific evidence supporting the safety or efficacy of opioids for long-term use. Defendants are well aware of the lack of such scientific evidence. While promoting opioids to treat chronic pain, Defendants failed to disclose the lack of evidence to support their use long-term and have failed to disclose the substantial scientific evidence that chronic opioid therapy actually makes patients sicker.

323. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use.

324. Substantial evidence exists that opioid drugs are ineffective to treat chronic pain, and actually worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments.⁸⁴

⁸³ The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

⁸⁴ A. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even

325. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

326. While opioids may work acceptably well for a while, when they are used on a long-term basis, function generally declines, as does general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.⁸⁵

327. The foregoing is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity. This is due partly to addiction and other side effects.

328. For example, as many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment, and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

D. DEFENDANTS' SCHEME TO CHANGE PRESCRIBER HABITS AND PUBLIC PERCEPTION

329. Before Defendants began the marketing campaign complained of herein, generally accepted standards of medical practice dictated that opioids should only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care.

patients who have past or active substance use disorders tend to receive higher doses of opioids. K. Seal, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940 (2012).

⁸⁵ See A. Rubenstein, *Are we making pain patients worse?* Sonoma Medicine (Fall 2009).

In those instances, the risks of addiction are low or of little significance.

330. The market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief. Defendants recognized that if they could sell opioids not just for short term pain relief but also for long-term chronic pain relief, they could achieve blockbuster levels of sales and their profits. Further, they recognized that if they could cause their customers to become physically addicted to their drugs, they would increase the likelihood that their blockbuster profits would continue indefinitely.

331. Defendants knew that in order to increase their profits from the sale of opioids they would need to convince doctors and patients that long-term opioid therapy was safe and effective. Defendants needed, in other words, to persuade physicians to abandon their long-held apprehensions about prescribing opioids, and instead to prescribe opioids for durations previously understood to be unsafe.

332. Defendants knew that their goal of increasing profits by promoting the prescription of opioids for chronic pain would lead directly to an increase in health care costs for patients, health care insurers, and health care payors such as Plaintiff's assignors and Class Members.

333. Marshalling help from consultants and public relations firms, Defendants developed and executed a common strategy to reverse the long-settled understanding of the relative risks and benefits of chronic opioid therapy. Rather than add to the collective body of medical knowledge concerning the best ways to treat pain and improve patient quality of life, however, Defendants instead sought to distort medical and public perception of existing scientific data.

334. As explained more fully herein, Defendants, collectively and individually, poured vast sums of money into generating articles, continuing medical education courses ("CMEs"), and other "educational" materials, conducting sales visits to individual doctors, and supporting a network of professional societies and advocacy groups, which was intended to, and which did, create a new but phony "consensus" supporting the long-term use of opioids.

1. Defendants' Corruption of Scientific Literature

335. Rather than actually test the safety and efficacy of opioids for long-term use, Defendants led physicians, patients, and health care payors to believe that such tests had already been done. As set forth herein, Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature was, in fact, marketing material intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

336. To accomplish their goal, Defendants – sometimes through third-party consultants and/or front groups – commissioned, edited, and arranged for the placement of favorable articles in academic journals.

337. Defendants' plans for these materials did not originate in the departments within the Defendant organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in Defendants' marketing departments and with Defendants' marketing and public relations consultants.

338. In these materials, Defendants (or their surrogates) often claimed to rely on "data on file" or presented posters, neither of which are subject to peer review. Still, Defendants presented these materials to the medical community as scientific articles or studies, despite the fact that Defendants' materials were not based on reliable data and subject to the scrutiny of others who are experts in the same field.

339. Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even when Defendants knew that the articles distorted the

significance or meaning of the underlying study. Most notably, Purdue frequently cited a 1980 item in the well-respected New England Journal of Medicine, J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) New Eng. J. Med. 123 (1980) ("Porter & Jick Letter"), in a manner that makes it appear that the item reported the results of a peer reviewed study. It is also cited in two CME programs sponsored by Endo. Defendants and those acting on their behalf failed to reveal that this "article" is actually a letter-to-the-editor, not a study, much less a peer-reviewed study. The letter, reproduced in full below, states that the authors examined their files of hospitalized patients who had received opioids.

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER

HERSHEL JICK, M.D.

**Boston Collaborative Drug
Surveillance Program**

Waltham, MA 02154 Boston University Medical Center

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D.
Comprehensive drug surveillance. JAMA. 1970; 213-1455-60.

2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

340. The patients referred to in the letter were all treated prior to the letter, which was published in 1980. Because of standards of care prior to 1980, the treatment of those patients with opioids would have been limited to acute or end-of-life situations, not chronic pain. The letter notes that, when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor, indeed, is there any indication whether the patients were followed after they were discharged from the hospital or, if they were, for how long. None of these serious limitations was disclosed when Defendants and those acting

on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are rarely addictive.

341. Dr. Jick has complained that his letter has been distorted and misused – as indeed it has.

342. Defendants worked to not only create and promote favorable studies in the literature, but to discredit or suppress negative information. Defendants' studies and articles often targeted articles that contradicted Defendants' claims or raised concerns about chronic opioid therapy. In order to do so, Defendants – often with the help of third- party consultants – used a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

343. Defendants' strategy – to plant and promote supportive literature and then to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted those claims – was flatly inconsistent with their legal obligations. The strategy was intended to, and did, distort prescribing patterns by distorting the truth regarding the risks and benefits of opioids for chronic pain relief.

2. Defendants' Misuse of Treatment Guidelines

344. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are generally not experts, and who generally have no special training, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and relied on by third-party payors in determining whether they should pay for treatments for specific indications.

a. Federation of State Medical Boards (FSMB)

345. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from

Defendants.

346. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies" and taught not that opioids could be appropriate in limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

347. A 2004 iteration of the 1998 Guidelines and the 2007 book, Responsible Opioid Prescribing, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in this District.

348. The publication of Responsible Opioid Prescribing was backed largely by drug manufacturers. In all, 163,131 copies of Responsible Opioid Prescribing were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as the "leading continuing medication (CME) activity for prescribers of opioid medications."

349. Defendants relied on 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

b. AAPM/APS Guidelines

350. American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to

opioids was low.⁸⁶ The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Russell Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

351. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue.

352. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated in nationwide and in this District during the relevant time period, and were and are available online.

353. Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

c. Guidelines that Did Not Receive Defendants' Support

354. The extent of Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines – the authors of which did not accept drug company funding – reached very different conclusions.

355. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non- Cancer Pain, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate

⁸⁶ The Use of Opioids for the Treatment of Chronic Pain, APS & AAPM (1997). Available at <http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf>.

that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it.” ASIPP’s Guidelines further advise that “therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain.” ASIPP recommends long-acting opioids in high doses only “in specific circumstances with severe intractable pain” and only when coupled with “continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects.”⁸⁷

356. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the “routine use of opioids in the management of patients with chronic pain,” finding “at least moderate evidence that harms and costs exceed benefits based on limited evidence.”⁸⁸

357. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the U.S. Department of Veterans Affairs (“VA”) and Department of Defense (“DOD”) in 2010, notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.⁸⁹

E. DEFENDANTS’ PROMOTION OF THEIR OPIOID DRUGS WAS ALSO DECEPTIVE

358. While Defendants worked in concert to expand the market for opioids, they also

⁸⁷Laxmaiah Manchikanti, et .al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

⁸⁸ *American College of Occupational and Environmental Medicine’s Guidelines for the Chronic Use of Opioids* (2011).

⁸⁹ Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010). Available at http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf.

worked to maximize their individual shares of that market. Each Defendant promoted opioids for chronic pain through sales representatives (which Defendants called “detailers” to deemphasize their primary sales role) and small group speaker programs to reach out to individual prescribers nationwide and in this District. By establishing close relationships with doctors, Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to allay individual prescribers’ concerns about prescribing opioids for chronic pain.

359. Defendants developed sophisticated methods for selecting doctors for sales visits based on the doctors’ prescribing habits. In accordance with common industry practice, Defendants purchase and closely analyze prescription sales data from IMS Health, a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above throughout the United States, including doctors in this District.

F. DEFENDANTS KNEW THAT THEIR MARKETING OF CHRONIC OPIOID THERAPY WAS FALSE, UNFOUNDED, AND DANGEROUS AND WOULD HARM PLAINTIFFS

360. Defendants made, promoted, and profited from their misrepresentations – individually and collectively – knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic pain were false and misleading. Cephalon and Purdue entered into settlements in the hundreds of millions of dollars to resolve criminal and federal charges involving nearly identical conduct. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers. Defendants expected and intended that their misrepresentations would induce doctors to prescribe, patients to use, and third-party payors to pay for their opioids for chronic pain.

361. When they began their deceptive marketing practices, Defendants recklessly disregarded the harm that their practices were likely to cause. As their scheme was implemented, and as reasonably foreseeable harm began to occur, Defendants were well aware that it was occurring. Defendants closely monitored their own sales and the habits of prescribing doctors, which allowed them to see sales balloon – overall, in individual practices, and for specific indications. Their sales representatives, who visited doctors and attended CME programs, knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to, and carefully monitored government and other data that tracked the explosive rise in opioid use, addiction, injury, and death.

G. DEFENDANTS ENTERED INTO AND ENGAGED IN A CIVIL CONSPIRACY

362. Defendants entered into a conspiracy to engage in the wrongful conduct complained of herein, and intended to benefit both independently and jointly from their conspiratorial enterprise.

363. Defendants reached an agreement between themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, and health care payors through misrepresentations or omissions regarding the appropriate uses, risks and safety of opioids.

364. This network is interconnected and interrelated, and relied upon Defendants' collective use of and reliance upon unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups. These materials were developed and funded collectively by Defendants, and Defendants relied upon the materials to intentionally mislead consumers, payors, and medical providers of the appropriate uses, risks and safety of opioids.

365. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, Defendants committed overt acts in furtherance of their conspiracy.

VII. CLASS REPRESENTATION ALLEGATIONS

A. CLASS DEFINITION

366. Plaintiffs, MSPA CLAIMS 1, LLC, MAO-MSO RECOVERY II, LLC, and MSP RECOVERY CLAIMS, SERIES LLC, in their capacity as assignees of certain Florida Medicaid Managed Care Plans and Providers, bring this Class Action on their own behalf and on behalf of all similarly-situated health care entities that provide health care benefits and additional services to Florida Medicaid beneficiaries (the “PLR Class”), in accordance with Florida Rule of Civil Procedure 1.220. The PLR Class is defined as follows:

All Florida Medicaid Managed Care Plans and Providers, including, but not limited to, Managed Care Organizations, Pre-Paid Inpatient Health Plans, Pre-Paid Ambulatory Health Plans, Health Maintenance Organizations, Managed Service Organizations, Provider Service Networks, Exclusive Provider Organizations, Accountable Care Organizations, Primary Care Case Management entities, Independent Physician Associations, and First Tier, Downstream and Related Entities, that entered into risk contracts with the Florida Agency for Health Care Administration (“AHCA”) and/or were licensed by AHCA to provide health care benefits and related services to Florida Medicaid beneficiaries through risk contracts with a Medicaid Managed Care Plan to provide health care, services, prescription drugs and supplies as well as items and services to Medicaid beneficiaries in the State of Florida between January 1, 2011 and the present date (the “Class Period”), who purchased, paid, provided reimbursement and/or possess the right to seek reimbursement from liable third-parties for the costs of prescription opioid drugs manufactured, marketed, sold, or distributed by the Defendants, for purposes other than resale, and/or who, during the same class period, incurred costs for treatments, hospitalizations, addiction and rehabilitation treatment, overdose or other opioid-related health-care services.

This class definition excludes (a) Defendants, their officers, directors, management, employees, subsidiaries and affiliates; and (b) any judges or justices involved in this action and any members of their immediate families.

367. Plaintiffs’ Assignors and the PLR Class have provided and paid for health care benefits and additional services to millions of Florida Medicaid beneficiaries, including, opioid-

related health-care services. Specifically, Plaintiffs' Assignors and the PLR Class were ultimately forced to pay for and absorb the losses related to the delivery of care, services and/or supplies, including, the delivery of prescription opioid medications, treatments, hospitalizations, addiction and rehabilitation treatment, overdose or other opioid-related health care services to their respective Florida Medicaid beneficiaries that vastly exceeded the capitated payments they received for these enrollees. Therefore, Plaintiffs, in their capacity as assignees of certain Florida Medicaid Managed Care Plans and Providers, bring this Class Action on their own behalf and on behalf of the PLR Class, that comprise (a) Florida injunctive class and/or (b) Florida damage classes and/or (c) Florida state-wide damage sub-classes, during the period from January 1, 2011, to the present.

368. As discussed in this Class Action Complaint, Defendants have enjoyed ill-gotten gains from the sales of prescription opioids at the expense of Plaintiffs' Assignors and the PLR Class suffering damages to their property and business. Such damages apply to all Class Members (and Plaintiffs as the rightful assignees of those organizations that assigned their rights to Plaintiffs). Class action law has long recognized that, when a company engages in conduct that has uniformly harmed a large number of claimants such as Plaintiffs' Assignors, Class Members and similarly-situated entities, class resolution is an effective tool to redress the harm.

369. Here, the PLR Class members have been deprived of property and money by being caused to pay for opioid-related health care costs including prescription, addiction and rehabilitation, overdose and alternative drug treatments incurred by their Medicaid beneficiaries as a direct result of Defendants engaging in racketeering activity and tortious conduct, as alleged throughout this Complaint.

370. The PLR Class is properly brought and should be maintained as a class action under

Florida Rule of Civil Procedure 1.220(b)(1)(A) or (b)(3), in that: (a) the Class and Subclasses are so numerous that joinder of all members is impracticable and prosecution of separate claims or defenses by or against individual members of the Class and respective Subclasses would create a risk of inconsistent or varying adjudications concerning individual members of the Class which would establish incompatible standards of conduct for the party opposing the class; (b) there are questions of law or fact common to the claim or defense of the representative party and the claim or defense of each member of the Class and respective Subclasses which predominate over any question of law or fact affecting only individual members of the Class and respective Subclasses; (c) class representation is superior to other available methods for the fair and efficient adjudication of the controversy; and (d) the Plaintiffs will fairly and adequately protect the interests of the Class and Subclasses.

B. NUMEROSITY

371. Numerous Florida Medicaid Managed Care Plans and Providers assigned their rights to Plaintiffs, each of these individual Managed Care Plans and Providers and the numerous members of the putative PLR Class have, in the aggregate, paid for and provided health care benefits and services to the millions of Florida Medicaid beneficiaries enrolled in Florida's SMMC program. Plaintiffs' Assignors and the PLR Class paid for and absorbed the losses related to the delivery of care, services and/or supplies, including, the delivery of prescription opioid medications, treatments, hospitalizations, addiction and rehabilitation treatment, overdose or other opioid-related health care services to their respective Florida Medicaid beneficiaries that vastly exceeded the capitated payments they received for these enrollees.

372. The disposition of these claims in a class action will be of benefit to the parties and to the Court. Under any circumstances, the PLR Class members are so numerous and so

geographically widespread throughout the State of Florida that joinder of all members would be impracticable.

373. Thus, the numerosity element for class certification is met under Rule 1.220(a)(1), Fla. R. Civ. P.

C. COMMONALITY

374. There are questions of law or fact common to all members of the PLR Class, which satisfy the commonalty element for class certification under Rule 1.220(a)(2), Fla. R. Civ. P.

375. Defendants' engaged in a pattern of fraudulent and deceptive acts, racketeering activity and unlawful conduct having a common, adverse effect on all purchasers and users of prescription opioids for long-term chronic pain leading to an opioid epidemic in the State of Florida, and directly impacting Plaintiffs' Assignors and the PLR Class who are left without an option but to pay for the opioid-related health-care costs and services. Therefore, common questions of law or fact are prevalent throughout the class, including, but not limited to:

- a. whether Defendants misrepresented the safety and efficacy of opioid drugs, to the financial detriment of the Class;
- b. whether Defendants engaged in a conspiracy to promote the sales of and suppress adverse information about opioid drugs;
- c. whether Defendants have made material misrepresentations of fact, or omit to state material facts regarding the addiction risks associated with opioid drugs, which material misrepresentations or omissions operate as a fraud and deceit upon the Class;
- d. whether Plaintiffs and the Class paid for more opioid drugs than for other efficacious drugs that were available at cheaper prices, and/or paid for more opioid drugs due to addiction, and/or paid for treatment including drug addiction treatment, and emergency medical care including the costs of Naloxone Hydrochloride (Narcan) as a result of the abuse, misuse, addiction and/or overdose of opioid drugs;
- e. whether persons who took opioid drugs are at increased risk of severe and permanent injuries, including addiction and overdose;

- f. whether, in marketing and selling opioid drugs, Defendants failed to disclose the dangers and risks to the health of persons ingesting the drug;
- f. whether Defendants failed to warn adequately of the adverse effects of opioid drugs, including addiction and overdose;
- g. whether Defendants misrepresented in their advertisements, promotional materials and other materials, among other things, the safety, potential side effects, and convenience of opioid drugs;
- h. whether Defendants knew or should have known that the ingestion of opioid drugs leads to serious adverse health effects;
- i. whether Defendants adequately tested opioid drugs prior to selling it;
- j. whether Defendants manufactured, marketed, distributed and sold opioid drugs notwithstanding their knowledge of the drugs' dangerous nature;
- k. whether Defendants knowingly omitted, suppressed and/or concealed material facts about the unsafe and defective nature of opioid drugs from government regulators, the medical community, health insurers and/or the consuming public;
- l. whether the Class has been damaged, and if so, the extent of such damages and/or the nature of the equitable relief, statutory damages, or punitive damages to which the Class is entitled;
- m. whether Defendants were and are unjustly enriched by its acts and omissions, at the expense of the Class;
- n. the amount of attorneys' fees, prejudgment interest, and costs of the suit to which the Class is entitled;
- o. whether Defendants engaged in conduct that violates Florida Civil RICO statutes in promoting the sales of and suppressing adverse information about opioid drugs; and
- p. whether Defendants engaged in a conspiracy to promote the sales of and suppress adverse information about opioid drugs in violation of Florida Civil RICO statutes.

D. TYPICALITY

376. Plaintiffs' claims are typical of the claims of the members of the PLR Class because Plaintiffs and the PLR Class sustained damages arising out of the Defendants' wrongful conduct

as detailed herein. Plaintiffs' and the PLR Class's claims have the same essential characteristics, arise from the same course of conduct and share the same legal theory.

377. Specifically, Plaintiffs' Assignors having expended substantial sums for the purchase of opioid drugs and treatment for their abuse, assert claims that are typical of the claims of the entire PLR Class, and will fairly and adequately represent and protect the interest of the PLR Class. As the putative class representatives, Plaintiffs possess the same interests and suffered the same injury as the other PLR Class members, which demonstrates a legally sufficient nexus between Plaintiffs' claims and the PLR Class's claims. Additionally, each of the Defendants' business practices, acts and omissions are materially the same with respect to the Plaintiffs' and PLR Class's claims, as will be the Defendants' legal defenses.

378. Plaintiffs' claims are, therefore, typical of the PLR Class and satisfy the typicality element for class certification under Rule 1.220(a)(3), Fla. R. Civ. P.

E. ADEQUACY OF REPRESENTATION

379. Plaintiffs will fairly and adequately represent and protect the interests of the PLR Class. Plaintiffs' claims are typical of the claims of the members of the PLR Class because they arise from the same pattern of fraudulent and deceptive acts, racketeering activity and unlawful conduct that gave rise to the claims of the PLR Class and are based on the same legal theories.

380. Plaintiffs' interests in vindicating these claims are shared with all members of the PLR Class and there are no interests adverse or antagonistic to those of the PLR Class.

381. Further, Plaintiffs have retained counsel who are competent and experienced in class action, and mass tort litigation, and also have no conflicts. In fact, two courts have already concluded that Plaintiffs' counsel is "willing and able to take an active role as class representative and advocate on behalf of all class members." *E.g., MSPA Claims I, LLC v. Ocean Harbor Cas.*

Ins., 2017 WL 477124 (Fla. 11th Cir. Ct. 2017); *MSPA Claims I, LLC v. IDS Property Casualty Ins. Co.*, Case No. 2015-27940-CA-01 (Fla. 11th Cir. Ct. 2017).

382. Accordingly, Plaintiffs have satisfied the adequacy of representation element for class certification under Rule 1.220(a)(4), Fla. R. Civ. P.

F. SUPERIORITY AND MANAGEABILITY

383. A class action is superior to all other available means for the fair and efficient adjudication of this controversy and, thus, should be maintained as a class pursuant to Rule 1.220(b)(3), Fla. R. Civ. P. Defendants acted in such a way that questions of law or fact predominate over any questions affecting only individual members. Defendants flagrantly misrepresented and misstated the efficacy of their opioid drugs for chronic opioid treatment. Without a class action, Defendants will remain free from responsibility for its course of deceptive and fraudulent conduct, and will be allowed to retain the proceeds that it obtained by deceiving Plaintiffs and the PLR Class into paying exorbitant amounts of money for unnecessary and ineffectual medication.

384. Proceeding with a class action is also superior to other methods for fair and efficient adjudication of this controversy because, *inter alia*, such treatment will allow a large number of similarly-situated assignors to litigate their common claims simultaneously, efficiently, and without the undue duplications of effort, evidence, and expense that several individual actions would induce; individual joinder of the individual members is wholly impracticable; the economic damages suffered by the individual class members may be relatively modest compared to the expense and burden of individual litigation; and the court system would benefit from a class action because individual litigation would overload court dockets and magnify the delay and expense to all parties. The class action device presents far fewer management difficulties and provides the

benefit of comprehensive supervision by a single court with economies of scale.

385. In addition, this case presents no unusual management difficulties. It is the custom and practice of CMS, AHCA and primary plans to maintain records in a detailed electronic format. Based on these practices, Plaintiffs maintain a reasonable methodology for generalized proof of Class-wide impact, using a software system (the “MSP System”) designed and developed by Plaintiffs and its counsel. The MSP System captures, compiles, synthesizes and analyzes large amounts of data in order to identify claims for reimbursement. This case will not present manageability problems as compared to non-electronic data driven class actions. Plaintiffs are capable of using the MSP System to identify and quantify PLR Class members’ claims, as it has done for its own claims. Two other courts have recognized the MSP System as a viable method to prove damages in substantially similar cases. *MSPA Claims 1, LLC v. Ocean Harbor Cas. Ins.*, 2017 WL 477124 (Fla. 11th Cir. Ct. 2017); *MSPA Claims 1, LLC v. IDS Property Cas. Ins. Co.*, Case No. 2015-27940 CA-01 (Fla. 11th Cir. Ct. 2017).

386. This Court is an appropriate forum for this dispute.

VIII. CAUSES OF ACTION

COUNT I

VIOLATION OF THE FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT, FLORIDA STATUTE § 501.201, ET SEQ. (“FDUTPA”)

387. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

388. This cause of action is brought pursuant to sections 501.201 to 501.213, Florida Statutes, which is known as the Florida Deceptive and Unfair Trade Practices Act (“FDUTPA”).

389. FDUTPA “shall be construed liberally to promote the following policies: (1) To simplify, clarify, and modernize the law governing consumer protection, unfair methods of competition, and unconscionable, deceptive, and unfair trade practices; (2) To protect the

consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce; [and] (3) To make state consumer protection and enforcement consistent with established policies of federal law relating to consumer protection. *See* § 501.202(2), Fla. Stat.

390. FDUPTA prohibits “unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce.” *See* 501.204(1), Fla. Stat.

391. At all times material to this cause of action, the Defendant manufacturers and distributors, along with the key opinion leaders they assisted and controlled, falsely and intentionally misrepresented to the general public, including to Plaintiffs’ Assignors and the PLR Class, the dangers of long-term opioid use to physicians, hospitals, pharmacists, patients, health insurers and government regulators, by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

392. The Defendants engaged in an intentional, decades-long pattern of unfair and deceptive acts relating to the efficacy of their respective opioid drugs, intentionally diminishing the associated health hazards and conspiring with key opinion leaders to increase their sales and profits despite the known risks and dangerous propensity of their drugs.

393. The Defendants intentionally overstated the benefits and downplayed the risks of the use of their opioids and aggressively marketed (directly and through key opinion leaders) these drugs to physicians and the Defendant distributors failed to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates as required under the Controlled Substances Act and Florida’s Controlled Substance Reporting program.

394. The representations by said Defendants were false, misleading and/or deceptive. In contrast, the Defendants knew their opioids were addictive, were not safe to be used for long-term chronic pain treatment, were being diverted and misused and were, in fact, dangerous and hazardous to the health and body of its users.

395. Representing that their prescription opioid drugs were, in fact, safe for long-term

chronic pain use is deceptive and has the capacity and tendency and effect of deceiving reasonable consumers who purchase and use the products, including the millions of Florida Medicaid beneficiaries that received opioid-related health care services. Reasonable consumers would believe that prescription opioids were safe to use for its intended purpose as a pain management treatment, based upon the Defendants' misrepresentations to that effect.

396. Plaintiffs' Assignors and the PLR Class, and their constituent members, relied on the Defendants' deceptive representations to their detriment.

397. The Defendants made, and make, the representation that their prescription opioid drugs are a safe method of treating long-term chronic pain conditions. Through their direct promotional efforts, along with those of the key opinion leaders and third-party Front Groups they assisted and controlled, and whose seemingly objective materials they distributed, Defendants accomplished exactly what they set out to do: change the institutional and public perception of the risk-benefit assessments and standard of care for treating patients with chronic pain. As a result, Florida doctors began prescribing opioids long-term to treat chronic pain—something most would never have considered prior to Defendants' campaign. But for the misleading information disseminated by Defendants, doctors would not, in most instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain.

398. Defendants' marketing of opioids caused health care providers to prescribe, and the Plaintiffs' Assignors and PLR Class to pay for, prescriptions of opioids to treat chronic pain. Because of Defendants' unbranded marketing, health care providers wrote, and the Plaintiffs' Assignors and PLR Class paid for, prescriptions of opioids for chronic pain that were filled not only with their drugs, but with opioids sold by other manufacturers. All of these prescriptions were caused by Defendants' fraudulent marketing and therefore all of them constitute false claims. Because, as required by CMS and AHCA, the Plaintiffs' Assignors and PLR Class are obligated to cover medically necessary and reasonably required care, they had no choice but to pay for these false and fraudulent claims.

399. The fact that Plaintiffs' Assignors and PLR Class would pay for these ineligible prescriptions was both the foreseeable and intended consequence of Defendants' fraudulent marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy with the intention of encouraging doctors to prescribe, and health insurers and providers such as Plaintiffs' Assignors and the PLR Class, to pay for long-term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

400. Defendants' misrepresentations were material to, and influenced, the Plaintiffs' Assignors 'and the PLR Class's decisions to pay claims for opioids for chronic pain (and, therefore, to bear their consequential costs in treating overdose, addiction, and other side effects of opioid use). In the first instance, the Plaintiffs' Assignors and the PLR Class would not have been presented with, or paid, claims for opioids that would not have been written but for Defendants' fraudulent and deceptive marketing. Second, the Plaintiffs' Assignors and the PLR Class have demonstrated that Defendants' marketing is material by taking further steps to ensure that the opioids are only prescribed and covered when medically necessary or reasonably required.

401. Defendants' misrepresentations related to the Plaintiffs' Assignors' and the PLR Class's requirement that medical treatments be medically necessary or reasonably required – a condition of payment for any medical treatment under Florida's SMMC. But for Defendants' fraudulent and deceptive marketing, prescribers would have accurately understood the risks and benefits of opioids and would not have prescribed opioids where not medically necessary or reasonably required to treat chronic pain. Misrepresentations as to, for example, whether patients were likely to become addicted to the drug, would be able to resume life activities, and would experience long-term relief were not minor or insubstantial matters, but the core of prescribers' decision-making.

402. Through their public statements, marketing, and advertising, Defendants' deceptions deprived the Plaintiffs' Assignors and the PLR Class of actual or presumptive

knowledge of facts sufficient to put them on notice of potential claims.

403. Through their reprehensible conduct described above, the Defendants, individually and collectively, engaged in unconscionable and deceptive acts and practices in violation of FDUPTA, the stated terms and intent of which is to protect consumers from unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce, by among other things:

- a. Misrepresenting the truth about how opioids lead to addiction;
- b. Misrepresenting that opioids improve function;
- c. Misrepresenting that addiction risk can be managed;
- d. Misleading doctors, patients, and payors through the use of misleading terms like “pseudoaddiction;”
- e. Falsely claiming that withdrawal is simply managed;
- f. Misrepresenting that increased doses pose no significant additional risks; and
- g. Falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment.

404. Plaintiffs’ Assignors and the PLR Class have been aggrieved and have suffered losses as a result of the Defendants’ violations of FDUPTA. By virtue of the foregoing unfair, unconscionable, and deceptive acts in the conduct of trade or commerce, Plaintiffs’ Assignors and the PLR Class were ultimately forced to pay for and absorb the losses related to the delivery of care, services and/or supplies, including, the delivery of prescription opioid medications, treatments, hospitalizations, addiction and rehabilitation treatment, overdose or other opioid-related health care services to their respective Florida Medicaid beneficiaries that vastly exceeded the capitated payments they received for these enrollees. Accordingly, Plaintiffs’ Assignors and the PLR Class have sustained injury as a direct and proximate result of Defendants’ illegal and wrongful conduct alleged herein and seek recovery of any and all costs, damages or losses sustained as a result of the provision of care, services and/or supplies, including, but not limited to, the

delivery of prescription opioid medications, treatments, hospitalizations, addiction and rehabilitation treatment, overdose or other opioid-related services.

405. The Defendants continue to violate FDUPTA through the present day.

406. By reason of the foregoing, the Defendants have violated FDUTPA and are liable to Plaintiffs and the PLR Class for the damages that they have suffered as a result of the Defendants' unconscionable actions, the amount of such damages to be determined at trial, and attorneys' fees and costs. Plaintiffs and the PLR Class further demand injunctive relief enjoining the Defendants from continuing to engage in, use, or employ any act, including advertisements, packaging, or other representations, prohibited by FDUTPA.

WHEREFORE, Plaintiffs, MSPA CLAIMS 1, LLC, MAO-MSO RECOVERY II, LLC, and MSP RECOVERY CLAIMS, SERIES LLC, and the PLR Class, pray for judgment against Defendants, ANDA, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, ABBOTT LABORATORIES, INC., RUSSELL PORTENOY, PERRY FINE, SCOTT FISHMAN, and LYNN WEBSTER, for damages in excess of Fifteen Thousand Dollars (\$15,000), for statutory

damages, for attorneys' fees and costs expended herein, for interest, and for such other and further relief both at law and in equity to which Plaintiffs and the PLR Class may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury.

**PREAMBLE FOR COUNTS II AND III – FLORIDA RACKETEER
INFLUENCED AND CORRUPT ORGANIZATION ACT (Florida Civil RICO)**

407. Counts II and III are brought pursuant to sections 895.01 – 895.06, Florida Statutes, which is known as the “Florida RICO (Racketeer Influenced and Corrupt Organization) Act” (hereinafter referred to as “Florida Civil RICO”).

408. Pursuant to Florida Statute § 895.03(1):

[i]t is unlawful for any person who has with criminal intent received any proceeds derived directly or indirectly, from a pattern of racketeering activity or through the collection of an unlawful debt to use or invest, whether directly or indirectly, any part of such proceeds, or the proceeds derived from the investment or use thereof, in the acquisition of any title to, or any right, interest, or equity in, real property or in the establishment or operation of any enterprise.

409. Pursuant to Florida Statute § 895.03(3):

[i]t is unlawful for any person employed by, or associated with, any enterprise to conduct or participate, directly or indirectly, in such enterprise through a pattern of racketeering activity or the collection of an unlawful debt.

410. Under § 895.02(5), Fla. Stat., an “Enterprise” means:

any individual, sole proprietorship, partnership, corporation, business trust, union chartered under the laws of this state, or other legal entity, or any unchartered union, association, or group of individuals associated in fact although not a legal entity; and it includes illicit as well as licit enterprises and governmental, as well as other, entities. A criminal gang, as defined in s. 874.03, constitutes an enterprise.

411. Under § 895.02(7), Fla. Stat., the “Pattern of racketeering activity” means:

engaging in at least two incidents of racketeering conduct that have the same or similar intents, results, accomplices, victims, or methods of commission or that otherwise are interrelated by distinguishing characteristics and are not isolated incidents, provided at least one of such incidents occurred after

the effective date of this act and that the last of such incidents occurred within 5 years after a prior incident of racketeering conduct. § 898.03(1)(a), Fla. Stat.

412. Florida Statute § 895.02(8) provides a list of the activities that that may constitute “Racketeering activity” under Florida RICO. Among those, § 895.02(8)(a)(4), Fla. Stat., includes unlawful acts under §§ 409.920 or 409.9201, “relating to Medicaid fraud,” and § 895.02(8)(a)(34), Fla. Stat., includes unlawful acts under Chapter 817, “relating to fraudulent practices, false pretenses, fraud generally, credit card crimes and patient brokering.”

413. Moreover, § 895.02(8)(b), Fla. Stat., specifically includes any conduct defined as “racketeering activity” under 18 U.S.C. § 1961(1), which includes, but is not limited to, acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), § 1512 (tampering with witnesses), and § 1952 (use of interstate facilities to conduct unlawful activity).

414. The Defendant opioid manufacturers, distributors and key opinion leaders, are part of a RICO Enterprise organized both formally and informally through business dealings and contractual relationships.

COUNT II

VIOLATION OF FLORIDA STATUTE § 895.03 – OPIOID DRUGS PROMOTION ENTERPRISE PURSUANT TO FLORIDA RICO

415. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

416. The Opioid Drugs Promotion Enterprise is an association-in-fact within the meaning of § 895.02(5), Fla. Stat., consisting of Defendants, including their employees and agents; and Front Groups, including their employees and agents; as well as external and other as yet unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioid Drugs Promotion Enterprise. All entities are persons within the meaning of § 895.03, Fla. Stat., and acted to enable Defendants to fraudulently market opioid drugs as scientifically

proven as safe and effective. The Opioid Drugs Promotion Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Opioid Drugs Promotion Enterprise was created and organized to effectuate a pattern of racketeering activity, and maintained systematic links for a common purpose: to ensure the prescription opioids for chronic pain. Each of these entities, including the Defendants, is a "person" distinct from the Opioid Drugs Promotion Enterprise.

417. Each of the Defendants, in concert with the Front Groups, as well as external and other as yet unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioid Drugs Promotion Enterprise, created and maintained systematic links for a common purpose-to aid in marketing opioid drugs as safe for treatment of chronic pain, while suppressing evidence to the contrary and improperly inducing physicians to prescribe opioid drugs for chronic pain. Each of the participants in the Opioid Drugs Promotion Enterprise received substantial revenue from the scheme to promote opioid drugs as safe for its intended uses. Such revenue was exponentially greater than it would have been if opioid drugs was marketed appropriately and the true safety risks of opioid drugs disclosed. All participants of the Opioid Drugs Promotion Enterprise were aware of Defendants' control over the activities of the Opioid Drugs Promotion Enterprise in promoting opioid drugs. Furthermore, each portion of the enterprise benefited from the existence of the other parts.

418. The Opioid Drugs Promotion Enterprise engaged in and affected interstate commerce, because *inter alia*, it marketed, promoted, sold, or provided opioid drugs to thousands of individuals and entities throughout the United States, including Florida.

419. The named Defendants exerted control over the Opioid Drugs Promotion Enterprise and management of the affairs of the Opioid Drugs Promotion Enterprise.

420. Defendants conducted and participated in the affairs of the Opioid Drugs Promotion Enterprise through patterns of racketeering activity pursuant to Florida Statute § 895.02(8)(b), which includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), § 1512 (tampering with witnesses), and § 1952 (use of interstate facilities to conduct

unlawful activity).

421. Defendants' fraudulent scheme consisted of, inter alia: deliberately misrepresenting the safety of Opioid Drugs so that the Plaintiffs' Assignors and PLR Class paid for the Defendants' opioid drugs for pain treatment and actively concealing and causing others to conceal, information about the true safety of opioid drugs for such pain treatment. The Opioid Drugs Promotion Enterprise concealed from the public, consumers, prescribers, health insurers and providers, like the Plaintiffs' Assignors and PLR Class, the serious risks and lack of corresponding benefits of using opioids for chronic pain. By making those representations, the Opioid Drugs Promotion Enterprise ensured that a larger number of opioid prescriptions would be written and filled for chronic pain. This translated into higher sales (and therefore profits) for Defendants.

422. The persons engaged in the Opioid Drugs Promotion Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Defendants. There is regular communication between Defendants and Front Groups, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Defendants and Front Groups share information regarding overcoming objections to the use of opioids for chronic pain. Defendants and the Front Groups functioned as a continuing unit for the purposes of implementing the Opioid Drugs Promotion Enterprise scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue the Opioid Drugs Promotion Enterprise existence.

423. At all relevant times, Front Groups were aware of Defendants' conduct, were a knowing and willing participant in that conduct, and reaped benefits from that conduct. Each Front Groups also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, health insurers and providers, including Plaintiffs' Assignors and the PLR Class. But for the Opioid Drugs Promotion Enterprise's unlawful fraud, Front Groups would have had the incentive to disclose the deceit by Defendants to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid

Drugs Promotion Enterprise's scheme, and reaped substantial benefits.

424. At all relevant times, the Defendant, KOLs, were aware of Defendants' conduct, were knowing and willing participants in that conduct, and reaped profits from that conduct. Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers, health insurers and providers, including Plaintiffs' Assignors and the PLR Class. Opioid Drugs Promotion Enterprise's unlawful fraud, KOLs would have been incentivized to disclose the deceit, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs perpetuated the Opioid Drugs Promotion Enterprise's scheme, and reaped substantial benefits.

425. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged communities in Florida, and throughout the United States, the Front Groups and KOLs did not challenge Defendants' misrepresentations, terminate their role in the Opioid Drugs Promotion Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

426. The Front Groups and KOLs participated in the conduct of the Opioid Drugs Promotion Enterprise, sharing the common purpose of marketing opioids for chronic pain and, through a pattern of racketeering activity, which includes multiple instances of mail fraud, and multiple instances of wire fraud, they knowingly made material misstatements or omissions as set forth herein above to Florida physicians, consumers, health insurers and providers, and the general public in furtherance of the fraudulent scheme.

427. Defendants' use of the mails and wires to perpetuate their fraud involved thousands of communications, including, but not limited to:

- a. communications with and among the enterprise participants that

- misrepresented the safety and risks of opioid drugs amongst themselves and others;
- b. communications with patients, health care insurers and providers, including Plaintiffs' Assignors and the PLR Class, inducing payments for opioid drugs by misrepresenting the safety and risks of opioid drugs;
- c. receiving the proceeds in the course of and resulting from Defendants' improper scheme;
- d. transmittal and receipt of monies from health insurers and providers, including, without limitation Plaintiffs' Assignors and the PLR Class, as well as governmental health organizations and programs, including without limitation Medicare and Medicaid; and
- e. transmittal and receipt of payments in exchange for, directly or indirectly, activities in furtherance of the Opioid Drugs Promotion Enterprise.

428. At all times during the fraudulent scheme, Defendants and the Fraud Participants including without limitation the KOLs and the Front Groups had a legal and ethical obligation of candor to and honest dealing with public and physicians, health insurers and providers and the medical community.

429. The conduct of the Opioid Drugs Promotion Enterprise described above constitutes "racketeering activity" within the meaning § 895.02(8), Fla. Stat., and 18 U.S.C. § 1961(1). Defendants' decisions and activity in connection with the Opioid Drugs Promotion Enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of § 895.02(7), Fla. Stat., and 18 U.S.C. § 1961(5).

430. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiffs' Assignors and the PLR Class. Each such racketeering activity was related had similar purposes, involved similar or the same participants, and methods of commission, and had similar results affecting the same or similar victims, including Plaintiffs' Assignors and the PLR Class. Defendants' racketeering activities were part of their ongoing business and constitute a continuing threat to the property of Plaintiffs' Assignors and the PLR Class.

431. Plaintiffs' Assignors and the PLR Class have been injured in their property by

reason of these violations in that Plaintiffs' Assignors and the PLR Class paid for opioid drugs, and for treatment related to opioid addiction and abuse that they would not have paid had Defendants not engaged in this pattern of racketeering activity.

432. The injuries to Plaintiffs' Assignors and the PLR Class were directly and proximately caused by Defendants' racketeering activity.

433. Plaintiffs' Assignors and the PLR Class, as well as Managed Care Organizations, Pre-Paid Inpatient Health Plans, Pre-Paid Ambulatory Health Plans, Health Maintenance Organizations, Managed Service Organizations, Provider Service Networks, Exclusive Provider Organizations, Accountable Care Organizations, Primary Care Case Management entities, Independent Physician Associations, and First Tier, Downstream and Related Entities, directly relied on the racketeering activities of the Defendants and the Opioid Drugs Promotion Enterprise. Plaintiffs' Assignors and the PLR Class, both directly and indirectly, relied on the representations as to the efficacy and safety of opioid drugs as promoted by Defendants. Because Defendants controlled all knowledge of the tests upon which the claims of opioid drugs' efficacy and safety were based, as well as other members of the medical community and consuming public were obligated to rely on Defendants' and the Opioid Drugs Promotion Enterprise's representations about opioid drugs. Further, Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about the use of opioid drugs for chronic pain.

434. By virtue of these violations of § 895.03(1) and (3), Fla. Stat., Defendants are liable to Plaintiffs' Assignors and the PLR Class for three times the damages sustained, plus the costs of this suit, including reasonable attorneys' fees.

435. By reason of the foregoing, and as a direct and proximate result of Defendants' unlawful racketeering activity, Plaintiffs' Assignors and the PLR Class have suffered damages. Plaintiffs' Assignors and the PLR Class are entitled to compensatory damages, equitable and declaratory relief, costs and reasonable attorneys' fees.

WHEREFORE, Plaintiffs, MSPA CLAIMS 1, LLC, MAO-MSO RECOVERY II, LLC,

and MSP RECOVERY CLAIMS, SERIES LLC, and the PLR Class, pray for judgment against Defendants, ANDA, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, ABBOTT LABORATORIES, INC., RUSSELL PORTENOY, PERRY FINE, SCOTT FISHMAN, and LYNN WEBSTER, for damages in excess of Fifteen Thousand Dollars (\$15,000), for statutory damages, including treble damages, for attorneys' fees and costs expended herein, for interest, and for such other and further relief both at law and in equity to which Plaintiffs and the PLR Class may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury.

COUNT III

VIOLATION OF FLORIDA STATUTE § 895.03 – RICO CONSPIRACY PURSUANT TO FLORIDA RICO

436. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

437. Section 895.03(4) of Florida RICO provides that "it is unlawful for any person to conspire or endeavor to violate any of the provisions of subsection (1), subsection (2), or subsection (3)."

438. Defendants have violated § 895.03(4), Fla. Stat., by conspiring to violate §§ 895.03(1) and (3). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Opioid Drugs Promotion Enterprise described previously through a pattern of racketeering activity. The Defendants conspired with, *inter alia*, publicists, sales representatives, medical professionals, the KOLs, the Front Groups, academics and other intermediaries to promote opioid drugs for chronic pain, and suppress information about the harms known to result from opioid drugs use.

439. Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiffs' Assignors and the PLR Class of money.

440. The nature of the above-described Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an § 895.03(4), Fla. Stat., violation of RICO by conspiring to violate §§ 895.03(1) and (3), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

441. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating § 895.03(4), Fla. Stat., by conspiring to violate §§ 895.03(1) and (3), Fla. Stat., Plaintiffs' Assignors and the PLR Class have been and continue to be injured in their business or property as set forth more fully above.

442. Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts that fall within the purview of § 895.02(8)(b), Fla. Stat.:

- a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§

1341 and 1342;

- b. Multiple instances of mail fraud violation of 18 U.S.C. §§ 1341 and 1346;
- c. Multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346;
- d. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952;
- e. Multiple instances of Medicaid fraud in violation of §§ 409.920 or 409.9201, Fla. Stat.; and/or
- f. Multiple instances of Fraud in violation of Florida Statutes, Chapter 817.

443. Defendants' violations of the above Florida and federal laws and the effects thereof detailed above are continuing and, upon information and belief, will continue into the future unless enjoined by this Court.

444. Plaintiffs' Assignors and the PLR Class have been injured in their property by reason of these violations in that Plaintiffs' Assignors and the PLR Class have made paid for opioid drugs; and the treatment related to the misuse, addiction and/or overdose of opioid drugs that it would not have made had Defendants not conspired to violate §§ 895.03(1) and (3), Fla. Stat.

445. Injuries suffered by Plaintiffs' Assignors and the PLR Class were directly and proximately caused by Defendants' racketeering activity as described above.

446. Plaintiffs' Assignors and the PLR Class, as well as Managed Care Organizations, Pre-Paid Inpatient Health Plans, Pre-Paid Ambulatory Health Plans, Health Maintenance Organizations, Managed Service Organizations, Provider Service Networks, Exclusive Provider Organizations, Accountable Care Organizations, Primary Care Case Management entities, Independent Physician Associations, and First Tier, Downstream and Related Entities, directly relied on the racketeering activities of the Defendants and the Opioid Drugs Promotion Enterprise. Plaintiffs' Assignors and the PLR Class, both directly and indirectly, relied on the representations as to the efficacy and safety of opioid drugs as promoted by Defendants. Because Defendants controlled all knowledge of the tests upon which the claims of opioid

drugs' efficacy and safety were based, as well as other members of the medical community and consuming public were obligated to rely on Defendants' and the Opioid Drugs Promotion Enterprise's representations about opioid drugs. Further, Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about the use of opioid drugs for chronic pain.

447. By virtue of these violations of § 895.03(4), Fla. Stat., Defendants are liable to Plaintiffs' Assignors and the PLR Class for three times the damages sustained, plus the costs of this suit, including reasonable attorneys' fees.

448. By reason of the foregoing, and as a direct and proximate result of Defendants' conspiracy to engage in unlawful racketeering activity, Plaintiffs' Assignors and the PLR Class have suffered damages. Plaintiffs' Assignors and the PLR Class are entitled to compensatory damages, equitable and declaratory relief, costs and reasonable attorneys' fees.

WHEREFORE, Plaintiffs, MSPA CLAIMS I, LLC, MAO-MSO RECOVERY II, LLC, and MSP RECOVERY CLAIMS, SERIES LLC, and the PLR Class, pray for judgment against Defendants, ANDA, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, MCKESSON CORPORATION,

CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, ABBOTT LABORATORIES, INC., RUSSELL PORTENOY, PERRY FINE, SCOTT FISHMAN, and LYNN WEBSTER, for damages in excess of Fifteen Thousand Dollars (\$15,000), for statutory damages, including treble damages, for attorneys' fees and costs expended herein, for interest, and for such other and further relief both at law and in equity to which Plaintiffs and the PLR Class may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury.

COUNT IV

**PRIVATE CAUSE OF ACTION UNDER THE FLORIDA
MEDICAID THIRD-PARTY LIABILITY ACT, FLORIDA STATUTE § 409.910**

449. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

450. This cause of action is brought pursuant to section 409.910, Florida Statutes, which is known as the "Medicaid Third-Party Liability Act."

451. At times material hereto, the Defendant manufacturers and distributors, along with the KOLs they assisted and controlled, falsely and/or carelessly misrepresented to the general public, including to Plaintiffs' Assignors and the PLR Class, the dangers of long-term opioid use to physicians, pharmacists, and patients by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

452. The Defendants engaged in an intentional, decades-long pattern of unfair and deceptive acts relating to the efficacy of their respective opioid drugs, intentionally diminishing the associated health hazards and conspiring with key opinion leaders to increase their sales and profits despite the known risks and dangerous propensity of their drugs.

453. The Defendants intentionally overstated the benefits and downplayed the risks of the use of their opioids and aggressively marketed (directly and through key opinion leaders) these drugs to physicians and the Defendant distributors failed to monitor, detect, investigate, refuse and

report suspicious orders of prescription opiates as required under the Controlled Substances Act.

454. The representations by said Defendants were false, misleading and/or deceptive. In contrast, the Defendants knew their opioids were addictive, were not safe to be used for long-term chronic pain treatment, were being diverted and misused and were, in fact, dangerous and hazardous to the health and body of its users.

455. Through their conduct described above, the Defendants have engaged in unconscionable and deceptive acts.

456. Representing that their representative prescription opioids were, in fact, safe is deceptive and has the capacity and tendency and effect of deceiving reasonable consumers who purchase and use the products, including the millions of Florida Medicaid beneficiaries that were enrolled in the Plaintiffs' Assignors' and PLR Class' MMA or LTC plans. Reasonable consumers would believe that prescription opioids were safe to use for its intended purpose as a pain management treatment, based upon the Defendants' misrepresentations to that effect.

457. Plaintiffs' Assignors and the PLR Class, as well as their constituent Medicaid beneficiaries, relied on the Defendants' deceptive representations to their detriment.

458. The Defendants made, and make, the representation that their prescription opioid drugs are a safe method of treating long-term chronic pain conditions.

459. Plaintiffs' Assignors and the PLR Class, as "payors of last resort," stand in the same shoes as AHCA. They entered into risk contracts with AHCA as a Medicaid MCO and/or were licensed by AHCA to provide health care benefits and related services to Florida Medicaid beneficiaries through risk contracts with a Medicaid MCO to provide such services.

460. Plaintiffs' Assignors and the PLR Class were forced to pay for and absorb the losses related to the delivery of care, services and/or supplies, including, the delivery of prescription opioid medications, treatments, hospitalizations, addiction and rehabilitation treatment, overdose or other opioid-related health care services to their respective Florida Medicaid beneficiaries that

vastly exceeded the capitated payments they received for these enrollees. Accordingly, Plaintiffs and the PLR Class are entitled to seek recovery for these losses and damages sustained as a direct and proximate result of the Defendants' intentional and tortious acts and/or omissions as "payors of last resort."

461. Plaintiffs' Assignors and the PLR Class are contractually and/or statutorily authorized to pursue reimbursement for these losses from the Defendants. *See* § 409.910, Fla. Stat. and Federal Register, Vol. 81, No. 88, at 27771. Plaintiffs' Assignors and the PLR Class seek to recover the following losses or damages from the Defendants:

- a. The Medicaid fee schedule amount for the service furnished;
- b. The full amount the insurer is legally liable to pay for the service;
- c. The amount the MCO allows for the service;
- d. The amount the provider bills for the service; or
- e. The monthly capitation payment for the service.

462. Accordingly, Plaintiffs' Assignors and the PLR Class have the statutory and contractual right to pursue and recover third-party liability claims from the Defendants as set forth under the Medicaid Third-Party Liability Act.

463. By reason of the foregoing, the Defendants are liable to Plaintiffs' Assignors and the PLR Class for the damages that they have suffered as a result of the Defendants' actions, the amount of such damages to be determined at trial.

WHEREFORE, Plaintiffs, MSPA CLAIMS 1, LLC, MAO-MSO RECOVERY II, LLC, and MSP RECOVERY CLAIMS, SERIES LLC, and the PLR Class, pray for judgment against Defendants, ANDA, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., PURDUE PHARMA, L.P., PURDUE

PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, ABBOTT LABORATORIES, INC., RUSSELL PORTENOY, PERRY FINE, SCOTT FISHMAN, and LYNN WEBSTER, for damages in excess of Fifteen Thousand Dollars (\$15,000), for interest, and for such other and further relief both at law and in equity to which Plaintiffs and the PLR Class may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury.

COUNT V

FRAUDULENT CONCEALMENT

464. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs.

465. At all relevant times, the Manufacturer and Distributor Defendants, along with the Key Opinion Leaders they assisted and controlled, intentionally, willfully, and/or recklessly, with the intent to deceive, fraudulently concealed or omitted material information not otherwise known or available, knowing that the material was false or misleading, or failed to disclose a material fact

concerning the health effects or addictive nature of their respective prescription opioid drugs or both.

466. At all relevant times, the Defendants misrepresented and/or concealed material facts concerning the addictive and dangerous nature of their prescription opioid drugs, to consumers, including Plaintiffs' Assignors and the PLR Class, with the knowledge of the falsity of their misrepresentations.

467. At all relevant times, upon information and belief, the misrepresentations and concealments concerning their prescription opioid drugs that were manufactured, distributed, promoted and/or sold by the Defendants include, but are not limited to, the following:

- a. The Defendants intentionally misrepresented to Plaintiffs' Assignors and the PLR Class and the public the truth about how opioids lead to addiction;
- b. The Defendants knowingly misrepresented that opioids improve function;
- c. The Defendants misrepresented that addiction risk can be managed;
- d. The Defendants misled doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"
- e. The Defendants falsely claimed that withdrawal is simply managed;
- f. The Defendants misrepresented that increased doses pose no significant additional risks;
- g. The Defendants falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

468. At all relevant times, the Defendants actively, knowingly, and intentionally concealed and misrepresented these material facts to Plaintiffs' Assignors and the PLR Class and the consuming public with the intent to deceive the Plaintiffs' Assignors, the PLR Class and public, and with the intent that consumers would purchase and use their prescription opioid drugs.

469. At all relevant times, the consuming public, including Plaintiffs' Assignors and the PLR Class, would not otherwise have purchased or used these addictive and dangerous opioid

drugs for long-term chronic pain management they had been informed of the risks associated with the use of these drugs.

470. At all relevant times, Plaintiffs' Assignors and the PLR Class relied on the Defendants' misrepresentations concerning the safety and efficacy of these prescription opioid drugs, and its reliance was reasonably justified.

471. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiffs' Assignors and the PLR Class have incurred and continues to incur costs for opioid prescriptions in excess of those they would have otherwise incurred, payments for their insureds' treatment for opioid addiction, and payments for emergency hospital visits for their insureds' including payments for Naloxone Hydrochloride (Narcan) resulting from opioid abuse and overdose. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiffs' Assignors and the PLR Class.

WHEREFORE, Plaintiffs, MSPA CLAIMS 1, LLC, MAO-MSO RECOVERY II, LLC, and MSP RECOVERY CLAIMS, SERIES LLC, and the PLR Class, pray for judgment against Defendants, ANDA, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC.,

ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, ABBOTT LABORATORIES, INC., RUSSELL PORTENOY, PERRY FINE, SCOTT FISHMAN, and LYNN WEBSTER, for damages in excess of Fifteen Thousand Dollars (\$15,000), for interest, and for such other and further relief both at law and in equity to which Plaintiffs and the PLR Class may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury.

COUNT VI

CONSPIRACY TO COMMIT FRAUD BY CONCEALMENT

472. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs.

473. At all relevant times, the Manufacturer and Distributor Defendants, along with the Key Opinion Leaders they assisted and controlled, agreed to conceal or omit information regarding the health effects or addictive nature of their respective prescription opioid drugs or both, with the intention that the Plaintiffs' Assignors, the PLR Class and the public would rely on the information to their detriment.

474. The Defendants' actions, and those of the Key Opinion Leaders, constitute a successful conspiracy to commit fraud by concealment.

475. Specifically, Defendants agreed and conspired to misrepresent and/or conceal material facts concerning the addictive and dangerous nature of their prescription opioid drugs, to consumers, including Plaintiffs' Assignors and the PLR Class, with the knowledge of the falsity of their misrepresentations.

476. At all relevant times, upon information and belief, the misrepresentations and concealments concerning their prescription opioid drugs that were manufactured, distributed, promoted and/or sold by the Defendants include, but are not limited to, the following:

- a. The Defendants intentionally misrepresented to Plaintiffs' Assignors, the PLR Class and the public the truth about how opioids lead to addiction;
- b. The Defendants knowingly misrepresented that opioids improve function;
- c. The Defendants misrepresented that addiction risk can be managed;
- d. The Defendants misled doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"
- e. The Defendants falsely claimed that withdrawal is simply managed;
- f. The Defendants misrepresented that increased doses pose no significant additional risks;
- g. The Defendants falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

477. At all relevant times, the Defendants actively, knowingly, and intentionally agreed and conspired to conceal and misrepresent these material facts to the Plaintiffs' Assignors, the PLR Class and the consuming public with the intent to deceive the Plaintiffs' Assignors, the PLR Class and public, and with the intent that consumers would purchase and use their prescription opioid drugs.

478. At all relevant times, the consuming public, including Plaintiffs' Assignors and the PLR Class, would not otherwise have purchased or used these addictive and dangerous opioid drugs for long-term chronic pain management they had been informed of the risks associated with the use of these drugs.

479. At all relevant times, Plaintiffs' Assignors and the PLR Class relied on the Defendants' misrepresentations concerning the safety and efficacy of these prescription opioid

drugs, and its reliance was reasonably justified.

480. As a direct and foreseeable consequence of Defendants' conspiracy to commit fraud by concealment, Plaintiffs' Assignors and the PLR Class have incurred and continue to incur costs for opioid prescriptions in excess of those they would have otherwise incurred, payments for their insureds' treatment for opioid addiction, and payments for emergency hospital visits for their insureds' including payments for Naloxone Hydrochloride (Narcan) resulting from opioid abuse and overdose. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiffs' Assignors and the PLR Class.

WHEREFORE, Plaintiffs, MSPA CLAIMS 1, LLC, MAO-MSO RECOVERY II, LLC, and MSP RECOVERY CLAIMS, SERIES LLC, and the PLR Class, pray for judgment against Defendants, ANDA, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, ABBOTT LABORATORIES, INC., RUSSELL PORTENOY, PERRY FINE, SCOTT FISHMAN, and

LYNN WEBSTER, for damages in excess of Fifteen Thousand Dollars (\$15,000), for interest, and for such other and further relief both at law and in equity to which Plaintiffs and the PLR Class may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury.

COUNT VII

**NEGLIGENCE AND GROSS NEGLIGENCE
(AGAINST MANUFACTURER DEFENDANTS)**

481. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs.

482. The Manufacturer Defendants, PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC and MALLINCKRODT LLC, at all times material, manufactured, designed, formulated, marketed, tested, promoted, supplied, sold, and/or distributed their respective prescription opioid drugs in the regular course of business.

483. At all relevant times, the Manufacturer Defendants had a duty to act with reasonable care in the design, development, marketing, labeling, manufacturing, formulating,

testing, monitoring, distribution, and sale of their respective prescription opioid drugs.

484. At all relevant times, the Manufacturer Defendants had a duty to act with reasonable care and to warn the Plaintiffs' Assignors and the PLR Class and the consuming public of the risk, dangers and addictive nature of their respective prescription opioid drugs.

485. At all relevant times, the Manufacturer Defendants knew or should have known that their respective prescription opioid drugs were unreasonably dangerous and defective for long-term chronic pain treatment and when used in a reasonably foreseeable manner.

486. The Manufacturer Defendants breached their duty to Plaintiffs' Assignors and the PLR Class and were otherwise negligent in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring, distribution, and/or sale of their respective prescription opioid drugs, which were inherently dangerous and defective, and unfit and unsafe for their intended and reasonably foreseeable uses.

487. The Manufacturer Defendants were further negligent in failing to accompany their respective prescription opioid drugs with proper warnings or adequate labeling regarding the dangerous and potentially fatal health risks associated with the use of their respective prescription opioid drugs, particularly when used for long-term chronic pain treatment, which was their intended or reasonably foreseeable use.

488. The Manufacturer Defendants' conduct, acts and/or omissions, as described throughout this Complaint, was so gross and flagrant as to show a reckless disregard or a conscious wanton, reckless indifference to consequences or a grossly careless disregard for the life, safety or rights of consumers, health care insurers and providers, like the Plaintiffs' Assignors and the PLR Class, and the Manufacturer Defendants actively and knowingly participated in such conduct, and/or its officers, directors or managers knowingly condoned, ratified, or consented to such

conduct.

489. The Plaintiffs' Assignors and the PLR Class are without fault and they would not have paid for inappropriate prescriptions, but for the wrongful conduct of the Manufacturer Defendants.

490. The Manufacturer Defendant's acts and/or omissions were a proximate cause of the over-prescription of the opioids and, hence, the excessive payment for inappropriate prescriptions paid for by Plaintiffs' Assignors and the PLR Class.

WHEREFORE, Plaintiffs, MSPA CLAIMS 1, LLC, MAO-MSO RECOVERY II, LLC, and MSP RECOVERY CLAIMS, SERIES LLC, and the PLR Class, pray for judgment against Defendants, PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, for damages in excess of Fifteen Thousand Dollars (\$15,000), for interest, and for such other and further relief both at law and in equity to which Plaintiffs and the PLR Class may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury.

COUNT VIII

NEGLIGENCE AND GROSS NEGLIGENCE
(AGAINST DISTRIBUTOR DEFENDANTS)

491. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs.

492. The Distributor Defendants, ANDA, INC., MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, and ABBOTT LABORATORIES, INC., at all times material, had a duty to exercise reasonable care in the distribution of prescription opioids.

493. The Distributor Defendants breached their duty of care by failing to monitor and reduce the distribution and/or diversion of opioids.

494. The Distributor Defendants placed their profit motives above their legal duty and enabled, encouraged and caused the over-prescribing and distribution of opioids.

495. The Distributor Defendants negligently failed to perform their duty to help to prevent the over-prescription of opioids and/or acted with gross negligence.

496. The Distributor Defendants' conduct, acts and/or omissions, as described throughout this Complaint, was so gross and flagrant as to show a reckless disregard or a conscious wanton, reckless indifference to consequences or a grossly careless disregard for the life, safety or rights of consumers, health care insurers and providers, like the Plaintiffs' Assignors and the PLR Class, and the Distributor Defendants actively and knowingly participated in such conduct, and/or its officers, directors or managers knowingly condoned, ratified, or consented to such conduct.

497. The Plaintiffs' Assignors and the PLR Class are without fault and they would not have paid for inappropriate prescriptions, but for the wrongful conduct of the Distributor Defendants.

498. The Distributor Defendants' acts and/or omissions were a proximate cause of the over-prescription of the opioids and, hence, excessive payment for inappropriate prescriptions paid for by Plaintiffs' Assignors and the PLR Class.

WHEREFORE, Plaintiffs, MSPA CLAIMS 1, LLC, MAO-MSO RECOVERY II, LLC, and MSP RECOVERY CLAIMS, SERIES LLC, and the PLR Class, pray for judgment against Defendants, ANDA, INC., MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, and ABBOTT LABORATORIES, INC., for damages in excess of Fifteen Thousand Dollars (\$15,000), for interest, and for such other and further relief both at law and in equity to which Plaintiffs and the PLR Class may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury.

COUNT IX

UNJUST ENRICHMENT

499. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs.

500. Defendants acted willfully, wantonly, and with conscious disregard of the rights of the Plaintiffs' Assignors and the PLR Class.

501. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by Plaintiffs' Assignors and the PLR Class.

502. In exchange for the opioid purchases, and at the time Plaintiffs' Assignors and the PLR Class made these payments, Plaintiffs' Assignors and the PLR Class expected that Defendants had provided all of the necessary and accurate information regarding those risks and had not misrepresented any material facts regarding those risks.

503. Defendants, through the wrongful conduct described above, have been unjustly enriched at the expense of Plaintiffs' Assignors and the PLR Class.

504. In equity and good conscience, it would be unjust and inequitable to permit Defendants to enrich themselves at the expense of the Plaintiffs' Assignors and the PLR Class.

505. By reason of the foregoing, Defendants must disgorge its unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution to the Plaintiffs' Assignors and the PLR Class.

WHEREFORE, Plaintiffs, MSPA CLAIMS 1, LLC, MAO-MSO RECOVERY II, LLC, and MSP RECOVERY CLAIMS, SERIES LLC, and the PLR Class, pray for judgment against Defendants, ANDA, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, ABBOTT LABORATORIES, INC., RUSSELL PORTENOY, PERRY FINE, SCOTT FISHMAN, and LYNN WEBSTER, for damages in excess of Fifteen Thousand Dollars (\$15,000), for interest, and

for such other and further relief both at law and in equity to which Plaintiffs and the PLR Class may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury

IX. DEMAND FOR JURY TRIAL

506. Plaintiffs, MSPA CLAIMS 1, LLC, MAO-MSO RECOVERY II, LLC, and MSP RECOVERY CLAIMS, SERIES LLC, and the PLR Class, demand a trial by jury of all issues so triable as a matter of right.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, MSPA CLAIMS 1, LLC, MAO-MSO RECOVERY II, LLC, and MSP RECOVERY CLAIMS, SERIES LLC, in their capacity as assignees of certain Florida Medicaid Managed Care Plans and Providers, on their own behalf and on behalf of the PLR Class described herein, pray for the following relief:

- a. Find that this action satisfies the prerequisites for maintenance of a class action pursuant to Florida Rules of Civil Procedure 1.220(a) and (b)(1)(A) or (b)(3), and certify the respective Class;
- b. Designate Plaintiffs, MSPA CLAIMS 1, LLC, MAO-MSO RECOVERY II, LLC, and MSP RECOVERY CLAIMS, SERIES LLC, as representatives for the respective Class and Plaintiffs' undersigned counsel as Class Counsel for the respective Class; and
- c. Issue a judgment against Defendants that:
 - (1) Adjudges and decrees that Defendants violated the federal and state laws and legal standards invoked herein and are entitled to an award of damages to be determined at trial;
 - (2) Grants Plaintiffs and the PLR Class an award of reasonable attorneys' fees and as set forth in Count I;
 - (3) Grants Plaintiffs and the PLR Class an award for three times the damages sustained, plus the costs of this suit, including reasonable attorneys' fees and as set forth in Counts II and III;

- (4) Grants Plaintiffs and the PLR Class a reimbursement of damages for those moneys the Class is entitled to recover pursuant to their direct right of reimbursement as set forth within Count IV;
- (5) Grants Plaintiffs and the PLR Class pre-judgment and post-judgment interest as provided for by law or allowed by equity; and
- (6) Grants Plaintiffs and the PLR Class such other and further relief as the Court deems just and proper under the circumstances.

DATED this 16 day of February, 2018.

Respectfully submitted,

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